

**A FEASIBILITY STUDY ASSESSING HOME VIDEO TELEMETRY POLYSOMNOGRAPHY (HVTP)  
AS A DIAGNOSTIC PROCEDURE FOR ADULT PATIENTS UNDERGOING INVESTIGATION  
FOR PARASOMNIAS.**

by

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A Thesis Submitted to the University of Portsmouth

In Partial Fulfilment of the

Requirements for the Degree of

DOCTORATE IN HEALTH SCIENCE

May 2017

## **Abstract**

**Background:** The techniques used in assessing sleep disorders must endeavour to accurately document behavioural and physiological sleep features that they are designed to record, be acceptable to the patients and be economically viable. Present practice for laboratory based polysomnography, which is the gold standard for assessing sleep disorders, falls short of these expectations. Home recordings might help to obtain a more natural sleep, be less costly and preferable to patients. However, the feasibility of comprehensive home sleep studies is unclear due to the complexity of recording synchronised neurophysiological, cardiorespiratory and audio-visual signals in an unsupervised and non-dedicated environment.

The purpose of this study was to explore whether home video telemetry polysomnography can be performed successfully in people's own homes among patients referred to King's College Hospital telemetry unit to be investigated for parasomnias.

**Method:** A mixed method with two quantitative strands and one qualitative strand was adopted to assess data quality, cost aspects and acceptability. The three strands of this convergent parallel design were used to measure related but different facets of the study. A thirty-channel recording of physiological signals was synchronised with audio-visual signal. A numerical score point quality grading system developed by the researcher to assess sufficiency and readability of the recorded data was used. One on one semi-structured interview was used for the qualitative strand. Process based costing was used to assess cost viability.

**Results:** Twenty-one patients underwent two nights of the sleep study. The findings show that data was sufficient for sleep analysis in 97.6% of the nights recorded. The analysis shows that neurophysiological signals for sleep staging and for extended montage were readable or required minor adjustment in 95.1% of the studies. Cardiorespiratory signals were readable or required minor adjustments in 97.6% for electrocardiogram and 85.4% for respiratory signals. Video picture and contents were recognisable in 95.1%, and audio signal was present, audible and clear in 80.5%.

The procedure was acceptable to patients with burden of parasomnia, home environment related benefits and financial considerations emerging as main drivers for acceptance. The average cost was £617.15 compared to the standard average tariff of £998.49 for similar procedures within our hospital setting representing a saving of 38.2%.

**Conclusion:** The present feasibility study indicates that Home Video Telemetry Polysomnography is technically feasible, acceptable to the patients, and is economically viable.

## **Table of contents**

Abstract.....	ii
Table of contents.....	iv
Declaration.....	x
List of tables.....	xi
List of figures.....	xiii
List of appendices.....	xiv
List of abbreviations.....	xv
Acknowledgements.....	xvii
Dissemination.....	xviii

## **Thesis overview ..... 1**

## **Chapter 1 Introduction ..... 4**

1.1 Overview of sleep and sleep disorders .....	4
1.1.1 Sleep and wakefulness.....	4
1.1.2 Sleep disorders.....	5
1.2 Impact of sleep disorders .....	7
1.3 Parasomnias .....	8
1.4 Current methods of assessing sleep disorders including parasomnias .....	10
1.4.1 Clinical history and examination.....	12
1.4.2 Sleep diaries and questionnaires.....	13
1.4.3 Home video somnography recordings.....	14
1.4.4 Polysomnography (PSG) .....	15
1.5 Portable home sleep studies .....	21
1.6 Appraisal of current portable home sleep studies.....	21

## **Chapter 2 Literature review ..... 24**

2.1 Overview.....	24
2.2 Literature search strategy .....	25
2.3 Findings and discussion .....	30

2.3.1 Study types .....	30
2.3.2 Quality of data reported .....	30
2.3.3 Sleep disorders investigated.....	30
2.3.4 Study location .....	31
2.3.5 Acceptability .....	31
2.4 Discussion .....	31
2.5 Summary.....	33
2.6 Need for a comprehensive home-based sleep studies .....	34
<b>Chapter 3 General Methods .....</b>	<b>38</b>
3.1 Overview of the general methods.....	38
3.2 Approach .....	39
3.3 Research plan .....	39
3.4 Research design.....	41
3.5 Ethics.....	42
3.6 Participants.....	43
3.6.1 Participants' characteristics.....	43
3.6.2 Recruiting processes .....	44
3.6.3 Privacy and safety considerations .....	45
3.6.4 Safety consideration of the researcher .....	46
3.6.5 Sample size determination .....	46
3.6.6 Procedure .....	47
<b>Chapter 4: Home Video Telemetry Polysomnography (HVTP) data quality assessment</b>	<b>49</b>
4.1. Overview of data collection.....	49
4.2. Materials and methods .....	51
4.2.1. Capital Equipment .....	51
4.2.2 Consumables.....	53
4.2.3 Transport.....	55
4.3 Procedure for equipment assembly and patient set up .....	55
4.3.1 Neurophysiological parameters.....	58

4.3.2 Cardiorespiratory parameters .....	62
4.3.3 Audio-visual data .....	66
4.4. Procedure for data acquisition .....	67
4.4.1 Biological calibration.....	67
4.4.2 The overnight recording .....	68
4.5. Procedure for data quality analysis.....	68
4.5.1 Procedure for assessing the quality of physiological measurements .....	70
4.5.2 Procedure for assessing sufficiency in terms of duration and continuity of overnight recordings.....	72
4.5.3 Readability quality assessment for neurophysiological signals.....	72
4.5.4 Quality assessment for cardiorespiratory signals.....	74
4.5.5 Quality assessment for readability of audio-visual signals.....	76
4.5.6 Summary of data quality scoring procedure .....	80
4.6 Results .....	80
4.6.1 Patient characteristics for the present feasibility study.....	80
4.6.2. Data sufficiency according to duration and continuity for each night recording .....	84
4.6.3 Sleep scoring neurophysiological channels .....	85
4.6.4 Extended montage neurophysiological channels for event scoring .....	86
4.6.5. Cardiorespiratory channels.....	87
4.6.6 Audio-visual .....	88
4.6.8 Summary signal quality in terms of sufficiency and readability.....	90
4.7. Discussions.....	91
4.7.1 Summary of findings from the HVTP data .....	91
Feasibility .....	91
4.7.2. Quality evaluation of recorded data.....	93
4.7.3. The present ‘gold standard’ for sleep studies is not practical for all clinical scenarios .....	95
4.7.4. Technical considerations and challenges .....	97
4.7.5. Limitations .....	97

4.7.6. Implications.....	98
<b>Chapter 5: Patient acceptability of Home Video Telemetry Polysomnography (HVTP) 100</b>	
5.1 Methods .....	102
5.1.1 Participants .....	102
5.1.2 Data collection procedure .....	102
5.1.3 Ethical and privacy considerations .....	105
5.1.4 Analysis .....	106
5.2 Results .....	112
5.2.1 Burden of sleep problem as a motivator for accepting HVTP .....	115
5.2.2 Benefits of home environment for sleep studies .....	118
5.2.3 Burden of travelling to the hospital.....	122
5.2.4 Negative aspects of home monitoring technology .....	123
5.3 Discussion .....	126
5.3.1 HVTP process as a family issue .....	127
5.3.2 HVTP and territorial roles .....	128
5.3.3 Control and self determination .....	129
5.3.4 True reflection of reality of natural sleep.....	129
5.3.5 Economical considerations .....	130
5.3.6 HVTP and territorial encroachment.....	130
5.3.7. Impact of HVTP recording on privacy .....	131
5.4 Limitations of the study.....	133
5.4.1 Numbers and diversity of participants .....	133
5.4.2 Credibility.....	133
5.5 Conclusion .....	134
<b>Chapter 6: Cost aspects of home video telemetry polysomnography (HVTP)..... 136</b>	
6.1 Overview of HVTP costing .....	136
6.1.1. Objectives .....	137
6.1.2 Clinical verses research related costs .....	137
6.1.3 Cost perspective .....	138

6.1.4 Cost analysis time span.....	138
6.1.5 Clarification of the cost object in this study .....	138
6.2 Materials and methods .....	139
6.2.1 Process costing method.....	141
6.2.2 Resources identification .....	143
6.2.3 Resources quantification .....	145
6.2.4 Attaching monetary value to resources .....	147
6.2.5 Summing up the total cost for the cost object.....	152
6.3 Results .....	153
6.3.1 Demographics .....	153
6.3.2 Labour .....	153
6.3.3 Transport.....	157
6.3.4 The HVTP recording system.....	158
6.3.5 Consumables.....	160
6.4 Discussions.....	162
6.4.1 Main findings .....	163
6.4.2 Cost feasibility of HVTP .....	164
6.4.3 Main cost drivers .....	166
6.4.4 Limitations .....	168
6.4.5 Implications and significance.....	170
<b>Chapter 7: Overall discussions.....</b>	<b>172</b>
7.1. The overall findings .....	173
7.2 Limitations of the present study .....	174
7.3 Conclusions.....	177
7.4 Future studies.....	178
<b>Chapter 8: Reflection .....</b>	<b>180</b>
8.1 Introduction.....	180
8.2 The Journey .....	181
8.2.1 Motivation .....	181

8.2.2 Learning to learn .....	181
8.2.3 Understanding research .....	182
8.3.3. Dealing with obstacles .....	183
8.4 Future .....	185
<b>References .....</b>	<b>187</b>
<b>Appendices.....</b>	<b>201</b>

**Declaration of originality**

This thesis is submitted in partial fulfilment of the requirements of Doctor of Health Science in the School of Health Sciences and Social Work, University of Portsmouth, United Kingdom. Whilst registered as a candidate for the above degree, I have not been registered for any other research award. The results and conclusions embodied in this thesis are the work of the named candidate and have not been submitted for any other academic award.

Word count: 48,597

## List of Tables

Table 1 Categories of sleep disorders per ICSD-3 (AASM, 2014) .....	6
Table 2 Different diagnostic methods for assessing sleep disorders including parasomnias .....	11
Table 3 Summary of AASM recognised methods for sleep studies (Collop et al., 2007; Ferber et al., 1994) .....	18
Table 4 Search strategy results .....	26
Table 5 Reviewed articles by types of studies .....	27
Table 6 Summary showing the profile of parameters reported in different studies reviewed.....	29
Table 7 Three-point estimate to work out the possible number of subjects for the study .....	47
Table 8 HVTP recording parameters and settings .....	57
Table 9 Duration and continuity criteria of HVTP data variables .....	72
Table 10 Quality assessment for neurophysiological functional group as developed for this study. ....	73
Table 11 Respiratory signal quality assessments based on scorability.....	74
Table 12 Cardiac signal quality assessment based on quantity and ability to identify pertinent ECG components .....	75
Table 13 Picture quality elements adapted from the International Telecommunication Union (ITU, 2014) for assessing video quality.....	78
Table 14 Picture content quality scoring developed for this study reflecting technical adaptability of recording system to home environment.....	79
Table 15 Audio quality based on the International Telecommunication Union (ITU, 2014) listening scale. ....	80
Table 16 Referral pattern to the video telemetry unit at King’s College Hospital.....	81
Table 17 Study sample for those who were considered suitable for the study .....	83
Table 18 Suspected clinical profiles of the patients completing the study .....	84
Table 19 Duration and continuity quality score reflecting sufficiency of recorded data .....	85
Table 20 Sleep scoring neurophysiological channels rating per the criteria outlined in the procedure section .....	86
Table 21 Extended montage channels rating for seizure activity detection and movement scoring. ....	87
Table 22 Cardiorespiratory quality rating using criteria described in the procedure section.....	88
Table 23 Video quality rating .....	89
Table 24 Audio quality rating .....	89

Table 25 Summary showing quality in terms of sufficiency and readability of data recorded .....	90
Table 26 Main themes and subthemes.....	114
Table 27 The level of accuracy at the identification and valuation of cost components - modified from Tan et al. (2009) .....	140
Table 28 Process flow chart showing activities involved during HVTP .....	144
Table 29 Classification of HVTP transactions showing the type of activity and materials involved .....	146
Table 30 Labour related activities in the process of carrying HVT by different levels of staff .....	148
Table 31 Consumables usage in performing HVTP .....	150
Table 32 Average medical related labour costs based on four consultants' activities.....	154
Table 33 Physiologist's travel time between hospital and patients' homes.....	154
Table 34 Physiologist's time in patients' homes .....	155
Table 35 Physiologist's data review time .....	156
Table 36 Administrative related costs for non-clinical staff involved in HVTP process.....	157
Table 37 HVTP recording system costs per patient .....	159
Table 38 Cost of consumable items .....	160
Table 39 Labour related cost breakdown .....	162
Table 40 Summary of total cost of performing HVTP .....	162
Table 41 Personal development roadmap.....	182

## List of Figures

Figure 1 Sleep-wake spectrum showing the main three states of existence .....	4
Figure 2 Different clinical and/or research disciplines of sleep studies .....	16
Figure 3 Complex intervention stages adapted from Craig et al. (2013).....	40
Figure 4 Reliance lone worker protection device carried by researcher as name badge.....	46
Figure 5 Functional components of recording strategies .....	49
Figure 6 Example of HVTP recording showing video, neurophysiological and cardiorespiratory parameters.....	52
Figure 7 Assembly of the consumables for setting up HVTP recording.....	54
Figure 8 Assembled recording system consisting of a laptop, mounted camera and recording device.....	56
Figure 9 Recommended electrodes for sleep recording (AASM, 2007) .....	59
Figure 10 EOG electrode positions- electrodes labels F8 and F7 were used.....	60
Figure 11 Chin EMG for sleep scoring .....	61
Figure 12 EMG electrodes for extended montage .....	62
Figure 13 ECG electrode position for modified ECG lead 1 .....	63
Figure 14 Oro-nasal thermistor set up for recording the airflow .....	64
Figure 15 Respiratory effort electrode assembly .....	65
Figure 16 Fully set up patient for HVTP recording.....	66
Figure 17 Functional channel grouping showing the number and the function of signals recorded .....	71
Figure 18 Patient selection process .....	82
Figure 19 Thematic map showing themes and subthemes generated from analysis .....	113
Figure 20 An overview of process-based costing, adapted from Lee et al. (2003).....	142
Figure 21 Classifications of HVTP cost items .....	145
Figure 22 Rising level of complexity of sleep studies with expanded Type 1/Type 2 parameters .....	166

## List of appendices

Appendix 1 Patient information leaflet.....	201
Appendix 2 Partner’s information sheet .....	211
Appendix 3 Patient consent form.....	215
Appendix 4 Partner consent form .....	216
Appendix 5 Ethics approval- NRES SL14_ Favourable opinion.....	217
Appendix 6 KCH14-121 R&D approval letter.....	222
Appendix 7 HVP qualitative interview questions .....	225
Appendix 8 Organising transcribed data .....	227
Appendix 9 Letter to GP .....	235
Appendix 10 Form UPR16.....	236

## **List of abbreviations**

AASM	American Association of Sleep Medicine
ACR	Absolute Category Rating
AfC	Agenda for Change
cEMG	chin electromyography
ECG	electrocardiogram
EEG	electroencephalogram
EMG	electromyogram
EOG	electrooculogram
FDS	flexor digitorum superficialis
FNE	First Night Effects
HCS	healthcare science
HCSP	healthcare science practitioner
H-PSG	home polysomnography
HVTP	home video telemetry polysomnography
ICSD	International Classification of Sleep Disorders
ITU	International Telecommunication Union
LOC	left outer canthus
LPSG	laboratory polysomnography
LVTP	laboratory video telemetry polysomnography
NHS	National Health Service
NREM	non-rapid eye movement
NRES	National Research Ethics Service
PLMS	periodic limb movements in sleep
PSG	polysomnography
RBD	REM behaviour disorder
REM	rapid eye movement
RLS-UK	Restless Leg Society-United Kingdom
ROC	right outer canthus

sEEG sleep staging EEG  
SOPs standard operating procedures  
VET video EEG telemetry  
VPSG video polysomnography  
VTP Video Telemetry Polysomnography

## **Acknowledgements**

The work on this thesis has been inspiring, challenging and, in many ways, an interesting experience. It has been made possible by very special people to whom I am profoundly indebted.

My sincere thanks to Dr Rebecca Stores, my first supervisor, for invaluable advice and scientific input every step of the way. I am very greatly indebted for her support. I would also like to express my gratitude to Dr Nandini Mullatti, my work-based supervisor, for her constant support and encouragement. Many thanks go to Dr Louise Turner, my second academic supervisor, for her support and encouragement. I would like to thank Dr Susan Ormrod, a research facilitator at King's College Hospital, London, for her guidance through the research protocol and ethics process. I am also indebted to Dr Franz Brunnhuber, who originally floated the idea of home studies to me providing the initial input.

Many thanks go to my colleagues, especially Devyani Amin for their understanding and forbearing with me, even in the rough times during this course. I wish to sincerely thank my family, especially Winnie, my wife and friend, for her constant support and for always believing in me to complete this work. To the many others who have contributed and helped me in one way or other, directly or indirectly, I say, thank you.

## **Dissemination**

Muthinji, P., Mullatti, N., Amin, D., Brunnhuber, F. (2014).

Is home video telemetry-polysomnography (HVT-P) feasible?

Poster presented at the International Federation of Clinical Neurophysiology (IFCN) Congress, Berlin, Germany.

Muthinji, P., Mullatti, N., Amin, D., Brunnhuber, F., Turner, L & Stores, R. (2015).

Feasibility of Home Video Telemetry-Polysomnography (HVT-P).

Poster presented at the 10<sup>th</sup> OSET Congress, Turku, Finland.

Muthinji, P., Mullatti, N., Amin, D., Brunnhuber, F., Turner, L & Stores, R. (2017).

Feasibility of home video telemetry polysomnography for assessing sleep related neurological disorders.

Flash Presentation at the 1<sup>st</sup> International Congress on mobile health devices and seizure detection in epilepsy, Copenhagen, Denmark.

## **Thesis overview**

This thesis is a report on a feasibility study of home video telemetry polysomnography (HVTP) as a viable diagnostic procedure for patients referred to the telemetry unit of King's College Hospital for assessment of parasomnias. The thesis is divided into eight chapters.

Chapter One provides an introduction and overview of sleep and sleep disorders. Sleep and wakefulness as natural states of existence, and the importance of maintaining these natural states in an orderly cyclical fashion, are discussed. The development of sleep disorders as a consequence of disturbing this cycle, and the impact on the individual, others and society at large, are discussed. Current methods of assessing sleep disorders and their limitations are discussed with an emphasis on parasomnias.

Chapter Two presents a literature review of research studies that have reported on non-laboratory based video sleep studies. The research studies are evaluated by considering the parameters recorded with an emphasis on neurophysiological, cardiorespiratory and audio-visual signals, patients' perspectives on the procedures, and cost implications.

Chapter Three describes the general methods. A mixed method with three strands, combining quantitative and qualitative aspects of data quality, acceptability and cost implications, is outlined.

Chapters Four, Five and Six deal with HVTP data quality assessment, patient acceptability of HVTP and cost aspects of HVTP respectively and form the three strands of the mixed method study. Procedures of data collection, analysis and outcomes are outlined.

Chapter Seven provides an overall discussion of this programme of research. It provides an overview of the whole study and summarises the results. Methodological issues and limitations are discussed. In the conclusion, the feasibility of HVTP is reviewed and recommendation is made for a larger and preferably multicentre study.

Chapter Eight is a reflection on the journey of undertaking a Professional Doctorate programme, of which this thesis is a part. It gives an account of the learning experience

over the last five years. The motivation for undertaking the course, the learning achieved, the difficulties encountered, and personal sacrifices made while undertaking this course are discussed.

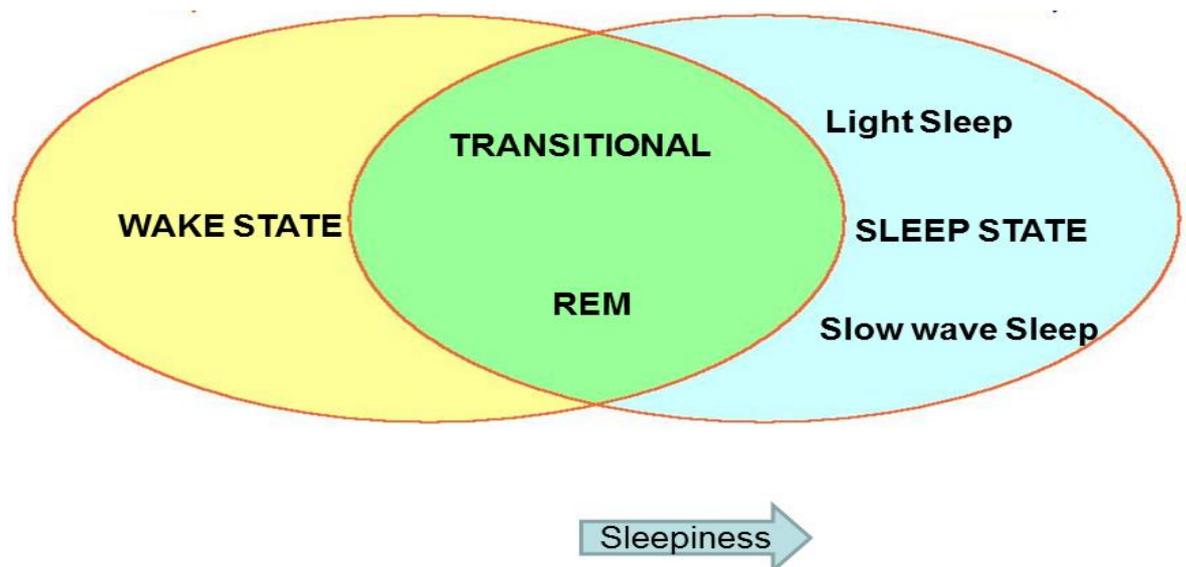


## Chapter 1 Introduction

### 1.1 Overview of sleep and sleep disorders

#### 1.1.1 Sleep and wakefulness

Sleep and wakefulness are fundamental behavioural and neurobiological states that characterise all higher animals, including human beings (Buysse, 2005). These two fundamentally different states occur in a 24-hour sleep-wake cycle (Dinges, 1989). The switch from wakefulness to sleep is not a discrete event, but a gradual process that entails a series of events taking place in a predictable order (Tryon, 1996). The 24-hour sleep-wake cycles are interspersed by transitional periods where neither true wakefulness nor sleep is present (Merica & Fortune, 2004). This is illustrated in Figure 1.



**Figure 1 Sleep-wake spectrum showing the main three states of existence**

The length of the wakeful period and external behavioural events influences the sleep-wake cycle (Saper, Scammell, & Lu, 2005). The control of sleep onset, duration and stage changes is poorly understood. It is thought that there are two sleep drives: homeostatic and circadian (Brown, Basheer, McKenna, Strecker, & McCarley, 2012). The coordinated alternating activity of several brain nuclei and transmitter systems regulates sleep-wake

states (Richter, Woods, & Schier, 2014). The homeostatic drive relies on sleep-promoting molecules, such as adenosine, which accumulate during wake and increases with the duration of wakefulness (Brown et al., 2012). The circadian drive, on the other hand, is controlled by the suprachiasmatic nucleus neurons in the hypothalamus (Inutsuka & Yamanaka, 2013; Saper et al., 2005).

In sleep, a person becomes relatively inactive and unaware of the environment, and the converse is true for wakefulness. Its purpose remains one of the unsolved scientific mysteries, despite the fact that humans spend roughly one-third of their life asleep (Steptoe, Peacey, & Wardle, 2006). Sleep is believed to be essential for physical and mental restoration and is recognised for its role in optimum daily functioning (Redline et al., 2004). Indeed, normal sleep is vital to the process of somatic growth and neurological development (Anstead, 2000); (Chervin, Archbold, Panahi, & Pituch, 2001). Sleep and sleep quality play a major role in many of our survival functions (Rye, 2004). Sleep is regulated by a complex set of genetic, biological, psychological, cultural and environmental factors (Guindalini et al., 2014). The quality and duration of sleep is also influenced by culture and lifestyles; therefore, it is strongly affected by cultural values, habits, and beliefs including bedtime routines or sleep schedules, the sleep environment, sleep literacy and autonomy around sleep (Jenni & Werner, 2011). Good quality sleep is characterised by sleep that is continuous and uninterrupted, and that progresses through an orderly succession of different sleep cycles with variable stages of sleep depth. Emotional state and behaviour, cognitive function and performance at school or work, family cohesion, mental health and also physical wellbeing can be affected by persistent sleep loss or poor quality sleep (Colten & Altevogt, 2006).

### **1.1.2 Sleep disorders**

People experiencing disturbances of the sleep-wake cycle typically present with one of four broad types of sleep-wake complaints:

- i. Insomnia (complaint of difficulty falling or staying asleep),
- ii. Hypersomnia (complaint of excessive daytime sleepiness),

- iii. Parasomnia (abnormal behavioural or physiological events occurring during sleep),
- iv. Circadian rhythm sleep disorders (disorders associated with the timing of sleep).

These four broad presentations of sleep-wake complaints combine to form multi-faceted, complex sleep disorder entities characterised by disturbances in the patients’ quantity, quality and timing of sleep, or in behaviours and physiological conditions associated with sleep.

The International Classification of Sleep Disorders revised version 3 (ICSD-3) (AASM, 2014) lists about 63 sleep disorders grouped into six categories, with a supplementary seventh category for those sleep disorders that cannot be fitted into the six major categories. These seven categories are summarised in Table 1.

**Table 1 Categories of sleep disorders per ICSD-3 (AASM, 2014)**

	<b>Sleep Disorder category</b>	<b>Selected Classifications</b>
1	Insomnia	Acute: adjustment insomnia, short-term insomnia, and transient insomnia. Chronic: depression/anxiety
2	Sleep-related breathing disorders	Central sleep apnoea, obstructive sleep apnoea, Sleep-related hypoventilation/hypoxemia syndromes
3	Central disorders of hypersomnolence	Narcolepsy with/without cataplexy, idiopathic hypersomnia (with/without long sleep time)
4	Circadian rhythm sleep – wake disorders	Time zone syndrome (jet lag), shift work sleep disorder, delayed sleep phase type, advanced sleep phase type, associated with medical condition

5	Parasomnias	<ul style="list-style-type: none"> <li>-Disorders of arousal (from non-rapid eye movement sleep [NREM]),</li> <li>-Parasomnias usually associated with rapid eye movement (REM)</li> <li>-Other parasomnias,</li> <li>-Isolated symptoms and normal variants</li> </ul>
6	Sleep-related movement disorders	Restless leg syndrome, periodic limb movement disorder, sleep-related bruxism
7	Other sleep disorders	Including sleep-related medical and neurological disorders

### 1.2 Impact of sleep disorders

Sleep disorders are common and at least 10% of the population suffers from a sleep disorder that is clinically significant and of public health importance (Ram, Seirawan, Kumar, & Clark, 2010). According to an earlier multinational survey, carried out in 2008, 56% (USA), 31% (Western Europe) and 23% (Japan) of the general population were affected by sleep problems (Léger, Poursain, Neubauer, & Uchiyama, 2008).

The cumulative effects of sleep disorders and sleep loss have been associated with a wide range of deleterious health consequences including an increased risk of hypertension, diabetes, obesity, depression, heart attack and stroke (Phillips, 2004). They also have a significant effect on health and quality of life (Pilcher et al., 1997), compromising many aspects of general health and psychological wellbeing (Reimer & Flemons, 2003). The elderly and those with psychiatric, neurological or medical conditions may be associated with higher rates of sleep disorders (Abad & Guilleminault, 2005); (Didde & Sigafos, 2001); (Phillips & Ancoli-Israel, 2001). They also present considerable problems to family life. A population longitudinal study by Strawbridge and others in 2004 suggested that

spouse's sleep problems negatively impact partners' health and wellbeing (Strawbridge et al., 2004).

Sleep-wake disorders have a high direct and indirect costs (Hillman et al., 2006). They present a considerable burden to the individual and society with high uptake of health services (Jennum & Kjellberg, 2010, 2011)

Sleep related vehicle accidents account for a considerable proportion of vehicle accidents, especially those on motorways and other monotonous roads (Horne & Reyner, 1999; Horne & Reyner, 1995) particularly in those with Sleep Apnoea Syndrome (Barbé et al., 1998); (Horstmann et al., 2000). They have also been associated with catastrophes including incidents in commercial nuclear power plants such as the Three Mile Island plant in Pennsylvania and the nuclear plant at Chernobyl as well as the Space Shuttle Challenger Accident (Mittler et al., 1988)

### **1.3 Parasomnias**

Parasomnias are listed as one of the six major sleep disorders in the current International Classification of Sleep Disorders (AASM, 2014). These are a group of sleep disorders encountered in neurology that often require polysomnography (PSG) studies within a neurophysiological diagnostic setting. The term 'parasomnia' is derived from the Greek word 'para' meaning around and the Latin term 'somnus' meaning sleep. It was first coined by Henri Roger in 1932 (Sullivan & Guilleminault, 2010). Parasomnias are either characterised by undesirable abnormal behavioural physical events and experiences (Vaughn & O'Neill, 2007), or physiological activities that occur in sleep-wake transitions during entry into sleep, within sleep, or during arousal from sleep. They are generally divided into four categories (AASM, 2014).

These categories are:

- i. Disorders of arousal (from NREM sleep), including confusional arousals, sleepwalking and sleep terrors;
- ii. Parasomnias usually associated with REM sleep, including nightmares, recurrent isolated sleep paralysis and RBD;

- iii. Other parasomnias, including sleep-related dissociative disorders, sleep enuresis, exploding head syndrome, sleep-related hallucinations, sleep-related eating disorders, unspecified parasomnia, parasomnia due to drug or substance abuse and parasomnia due to medical conditions;
- iv. Isolated symptoms and normal variants such as sleep talking.

Many of the behaviours expressed in parasomnias can become potentially dangerous for both the sleeper and those within their vicinity. This can lead to actions with dramatic consequences, and sometimes to complex medico-legal issues related to aberrant activities, for example, extreme interventional measures such as chaining themselves to the bed at night (Schenck & Mahowald, 2002), indecency (Thomas, 1997), violence (Siclari et al., 2010), homicide (Broughton et al., 1994); (Horn, 2004), rape (Koster, 2008), and so on. Furthermore, parasomnias affect not only the individual but also others. Bed partners, family members, and roommates may suffer sleep loss because of the parasomnia. It has been suggested that therapy of all parasomnias should include education regarding patient and bed partner safety as well as the avoidance of known precipitating factors (Matwiyoff & Lee-Chiong, 2010).

In addition to the direct consequences associated with parasomnia behaviour, parasomnias can present indirectly as insomnia or hypersomnia, which have significant adverse effect on an individual's sleep and, consequently, on their day to day functioning (Lopez et al., 2013). Compared to healthy individuals, individuals suffering from, sleep disorders, are less productive, have an increased health care utilization, and an increased likelihood of accidents (Colten & Altevogt, 2006). Sleep deficiency therefore has side effects not only at personal level, but also can cause harm on a larger scale including major accidents. These potential adverse effects of insufficient sleep on health, well-being and productivity, have far-reaching societal and economic consequences. It is, therefore, crucial that appropriate and adequate investigations are carried out to make the correct diagnosis in good time to allow intervention.

#### **1.4 Current methods of assessing sleep disorders including parasomnias**

There are no specific methods for assessing parasomnias. Table 2 shows different diagnostic methods ranging from subjective clinical methods to more complex objective methods. To obtain an overview of both the available measurements in sleep medicine and to choose the most appropriate method for specific populations, an overview of different methods is warranted. Parasomnias are of particular interest in this regard as the symptoms expressed in these conditions often overlap one another. The differential diagnosis encompasses a wide variety of undesirable and sometimes interacting behaviours arising from sleep. A complete evaluation with meticulous PSG and other methods as necessary is desirable.

**Table 2 Different diagnostic methods for assessing sleep disorders including parasomnias**

Assessment method	Limitations
Clinical history (Brietzke, Katz, & Roberson, 2004)	<ul style="list-style-type: none"> <li>-The subject of sleep disorders is poorly covered in medical education (Stores &amp; Crawford, 1998)</li> <li>-Patient or witness accounts are limited</li> <li>-Physical examination are inconclusive as parasomnias have no physical features of insult</li> <li>-Open to misinterpretations due to inadequacy of information provided</li> </ul>
Sleep diaries and sleep questionnaires (Landry, Best, & Liu-Ambrose, 2015; Senthilvel, Auckley, & Dasarathy, 2011).	<ul style="list-style-type: none"> <li>-Underutilised</li> <li>-Lack of time</li> <li>-Limited in patients with fluctuating level of awareness</li> </ul>
Home video (Ipsiroglu et al., 2015; Sivan, Kornecki, & Schonfeld, 1996)	These are of limited value if not synchronised with neurophysiology and cardiorespiratory parameters
Sleep studies (portable and full polysomnography [PSG]) (Collop et al., 2007).	<ul style="list-style-type: none"> <li>-These have none or limited neurophysiological channels</li> <li>-They have no synchronised video</li> </ul>

### **1.4.1 Clinical history and examination**

Experienced doctors obtain the clinical history in a problem-solving manner, which is focused on a specific clinical problem (Elstein & Schwarz, 2002). In order to obtain a focused clinical history appropriately, it is necessary to have the relevant knowledge of the causes of each symptom and the symptoms of each disease (Walters, 2007). Some reports indicate that a patient history may provide most of the information for diagnosis in most patients presenting with different kinds of clinical problems including sleep disorders (Hampton, Harrison, Mitchell, Prichard, & Seymour, 1975; Pryor et al., 1993; Schutte-Rodin, Broch, Buysse, Dorsey, & Sateia, 2008).

There is no doubt that sleep medicine is one area where good, directed, medical history taking is one of the more important diagnostic procedures. However, sleep medicine is generally disadvantaged in several ways. Firstly, there is little time devoted to sleep medicine training across the board. In the late 1990s, sleep physiology and pathology accounted for less than 2.5 hours of the American undergraduate curriculum (Rosen et al., 1998). Around the same time in the UK, undergraduate exposure to sleep medicine was less than 15 minutes in the preclinical period, and none in clinical education (Stores & Crawford, 1998). A more recent study in Japan concluded that in order to improve diagnostic reasoning skills, medical students should be trained in methods for inferring the correct diagnosis from the case history (Tsukamoto, Ohira, Noda, Takada, & Ikusaka, 2012).

Secondly, accurate information is difficult to obtain due to the nature of sleep problems. Obtaining accurate sleep history often requires collateral or collaborative information from bed partners or close relatives, especially regarding parasomnias. Detailed inquiries about sleep patterns and problems should be attempted, but recollections from the parents or bed partners about the respective sleep patterns and problems may well be incomplete or distorted. In addition, sleep is a very private matter and, in some cases, obtaining history can be extremely complex due to potentially relevant and interacting social, environmental, medical and psychological factors. A reliable description of any motor events occurring during the night is often difficult to collect from a witness or sleep

partner; this is because there might be no observer during sleep or, if present, they might not be fully awake themselves. In many cases, it is not possible to accurately diagnose conditions leading to abnormal behaviour or movement disorders during sleep by history alone. A review of the literature on the role of clinical history and physical examination in obstructive sleep apnoea/hypopnea syndrome concluded that clinical history and physical examination was not sufficient to make a diagnosis (Brietzke et al., 2004) and that there is no reason to believe the situation would be different in parasomnias. Therefore, in some cases at least, more objective assessment is needed for accuracy or, alternatively, when physiological information is required.

#### **1.4.2 Sleep diaries and questionnaires**

Screening tools for sleep studies are often necessary to classify patients based on their clinical symptoms, their physical examinations and their risk factors (Abrishami, Khajehdehi, & Chung, 2010). Sleep questionnaires and sleep diaries or sleep logs are detailed reports of sleeping and waking activities. They are widely used in clinical and research settings to gather information about sleep-wake patterns. Information may be recorded for as little as 24 hours or as long as several weeks. They provide subjective accounts of daily patterns that are particularly valuable when patients do not have easy access to laboratory settings, or even when symptoms occur infrequently, so that they are not likely to be captured in the recording period in a laboratory setting. For instance, the Consensus Sleep Diary which is a standardized, prospective tool for tracking nightly subjective sleep has been reported to be valid for clinical utility (Maich, Lachowski, & Carney, 2016). Furthermore a study by Gaina and others in 2004 showed that the correlation between subjective and objective sleep indices except sleep latency was quite high (Gaina, Sekine, Chen, Hamanishi, & Kagamimori, 2004).

Although data obtained from sleep diaries may be useful to clinicians and researchers, they are not a substitute for PSG recording. They have limited usefulness in patients with fluctuating day time vigilance, as seen in elderly patients (Landry, Best, & Liu-Ambrose, 2015). They are also limited due to other factors, including the time required to complete the questionnaires accurately (Yarnall, Pollak, Ostbye, Krause, & Michener, 2003). These

diagnostic instruments are not, therefore, routinely used to screen patients for sleep disorders (Sorscher, 2008).

### **1.4.3 Home video somnography recordings**

Video recording is a powerful non-contact method for monitoring sleep in adults and children as it is relatively cheap and does not disturb the natural sleep environment. Advances in the home computer industry are closely linked with audio and video digital recording systems. This means that patients can have their behaviour recorded at home and analysed by sleep specialists to try and understand the nature of sleep problems. For episodic disturbances at night, overnight video recordings alone can be highly instructive. Parents or bed partners can be encouraged to use their family video systems for recordings at home. The disparities between the video recording findings and the usual clinical descriptions of night time attacks are sometimes striking. Homemade videos are, therefore, useful tools for differentiating non-stereotyped from stereotyped behaviours, and for providing useful clues in distinguishing parasomnia from seizure (Tinuper et al., 2007).

In order to aid the diagnosis of sleep disturbances or assisting in the evaluation of the quality of sleep, video-somnogram recordings have been used to automatically detect and monitor respiratory movements and body position during sleep (Liao & Yang 2008); (Liao & Kuo, 2013). Video analysis for body position, however, is quite rare; it is particularly useful as a gold standard for assessing whether a suspected apnoeic event was real or not, and for identifying body position at any given point in the recording (Roebuck et al., 2014). Limb movement is also relatively easy to detect with video. Although current standard infrared video cameras with infrared light sources provide images of excellent quality and fine details of movement and behaviours can readily be perceived, continuous audio-visual recordings should be time-linked to the PSG to allow the association of physiological data with discrete behaviour. Home-made video recordings could be helpful in patients with difficult diagnosis, or when video-polysomnographic monitoring is not available (Ipsiroglu et al., 2015). Video-polysomnography represents the ideal diagnostic tool but, due to the difficulty of

capturing complex episodes in the sleep laboratory, home audio-video recordings of the episodes may help in the differential diagnosis (Mwenge, Brion, Ugucconi, & Arnulf, 2013; Plazzi, Vetrugno, Provini, & Montagna, 2005).

#### **1.4.4 Polysomnography (PSG)**

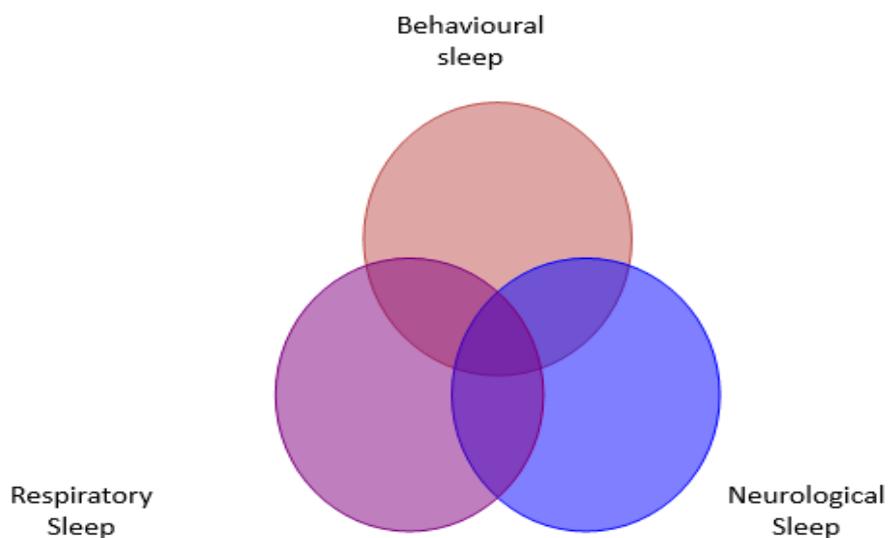
##### **Historical perspective**

The science of sleep emerged as a discipline because of the development of tools and techniques capable of detecting and recording brain activity and other physiological events that occur during the unique state of sleep. Prior to this development, sleep was seen as a passive state (Kirsch, 2011). In 1875, Richard Caton, a British scientist, reported to British Medical Association (BMA) that he had observed electrical impulses from the surfaces of living brains of animals (Caton, 1875). In 1929, Berger described the electrical activity of human brain scalp recordings, commonly referred to as electroencephalogram (EEG). He observed fluctuations of the ongoing alpha activity in relation to changes of the level of alertness. The waking alpha rhythm either disappeared or became a very low amplitude or less intense when the subject became drowsy or fell asleep. This was the first recording of the critical physiological parameter during sleep (Millett, 2001). In the late 1930s, Loomis and colleagues introduced the concept of continuously recording EEG activity through the night and, in doing so, identified different stages of sleep (Loomis, Harvey, & Hobart, 1935), (Loomis, Harvey, & Hobart, 1937). In 1953, Aserinsky, working in Kleitman's laboratory at the University of Chicago, added electrodes to record the eye movements he had observed through the eyelids of sleeping subjects, creating the electrooculogram (EOG). By waking subjects during intense periods of rapid eye movement (REM), he discovered that the REMs were associated with dreaming and, thus, discovered REM sleep (Aserinsky & Kleitman, 1953). Soon after in 1957, another researcher by name of William Dement, working in the same laboratory under Kleitman, established that REM alternated with NREM (sleep in cycles of approximately 90 minutes) (Dement & Kleitmann, 1957).

Objective sleep studies continued to be carried out using EEG and EOG until 1964; from this point on, Jacobson and colleagues reported that there was a loss of muscle tone at the onset of REM sleep (Jacobson, Kales, Lehmann, & Hoedemaker, 1964). Surface electromyogram (EMG) electrodes on the chin were added to the EEG and EOG recording parameters to better define the REM sleep state.

The understanding of sleep and sleep disorders has depended on the ability to simultaneously record and analyse these multiple physiological parameters during sleep. The modern practice of sleep medicine and the investigation of sleep related disorders owe much to the discovery of these three physiological key features. Holland and colleagues (1974) introduced the term polysomnography, in a paper presented to the Association of Psychophysiological Study of Sleep (Holland, Dement, & Raynal, 1974), to define these fundamental physiological parameters.

In the 1960s, researchers began to study patients with sleep complaints; from this foundation, sleep study was applied to different research and clinical settings heralding the merging of the discipline of sleep science with different clinical and research interests (Figure 2).



**Figure 2 Different clinical and/or research disciplines of sleep studies**

In 1956, a syndrome characterised by obesity-hypoventilation, also known as Pickwickian syndrome, was described (Bicklemann, Burwell, Robin, & Whaley, 1956). Patients with this syndrome frequently stop breathing for short periods of time during sleep, resulting in many partial awakenings from sleep, which leads to excessive sleepiness during the day (Olson & Zwillich, 2005). In these patients, when EEG showed signs of sleep, breathing ceased and arterial oxygen saturation levels dropped. Sleep studies in these patients showed that excessive daytime sleepiness was related to their sleep fragmentation, and not due to carbon dioxide poisoning (Jung & Kuhlo, 1965). In the mid-1960s, Gastaut, Tassinari, and Duron (1966), using measurements of mouth and nostril airflow, in addition to chest movements, demonstrated that the reason for the apnoeic events during sleep was the blockage of the upper airways during sleep, in spite of continuous respiratory effort, and that repetitive episodes of upper-airway obstruction were terminated by brief arousals that, in turn, fragmented nocturnal sleep. Obstructive sleep apnoea was discovered, and it was correctly postulated that sleep fragmentation was responsible for the excessive daytime somnolence observed in these patients. This new discovery in sleep studies inspired the evolution of PSG. When obstructive sleep apnoea became recognised as a common sleep disorder, cardiorespiratory variables were added to PSG as a standard feature (Ferber et al., 1994). Respiratory related sleep disorders are the most studied disorders by far and they remain the most common disorder associated with sleep studies (Toth & Bhargava, 2013).

Diagnostic assessment of apnoeas with the standard attended laboratory PSG continues to be the accepted diagnostic method used in most clinical and research settings. However, presumptions that accurate sleep apnoea evaluations can be performed more quickly, more conveniently and at a lower cost by the unattended recording of fewer parameters have led to a rapid increase in the use of portable equipment. The specifics of these portable devices, the methods by which they are applied, and the criteria by which individuals are selected for study, have not been standardised. To this end, the American Association of Sleep Medicine (AASM) has defined several objective technical methods

and devices for assessing sleep disorders, which are classified as Type 1-4 depending on their complexity (Collop et al., 2007; Ferber et al., 1994). Table 3 summarises the current recognised objective method for assessing sleep disorders.

**Table 3 Summary of AASM recognised methods for sleep studies (Collop et al., 2007; Ferber et al., 1994)**

Type 1	full attended PSG	(≥ 7 channels) in a laboratory setting
Type 2	full unattended PSG	(≥ 7 channels)
Type 3	limited channel devices that can be recorded in the laboratory or as portable	(Usually using 4-7 channels).
Type 4	1 or 2 channels usually using oximetry as 1 of the parameters. Usually recorded as part of a laboratory setting or as a stand-alone portable device.	

Although these procedures are mainly aimed at respiratory sleep disorders, they form the basis for procedures used in the diagnosis of other non-respiratory sleep disorders. Whereas all four types can be regarded as some form of sleep study, it would not be accurate to equate all of them to PSG, as some of them do not have all the parameters required in standard PSG. The term PSG, as the standard for the objective assessment of sleep physiology, must include the EEG, the EOG and the EMG as a minimum.

### **Polysomnography as the gold standard**

Polysomnography, as specified in the European Guidelines, is used as the reference method in the diagnostic procedures of sleep medicine (Kushida et al., 2005; Pevernagie et al., 2006). Among the technical methods for evaluation of sleep disorders, it is by far the most important tool. It is an objective method for the documentation and quantification of the physiological manifestations of sleep and sleep disorders, combining

both neurophysiological and respiratory features simultaneously. Apart from the basic typical characteristic sleep features of at least one channel EEG to measure brain activity, two EOGs to measure eye movements, and one EMG to measure muscle tone, sometimes more EEG/EMG and cardiorespiratory monitoring channels are added. Certain sleep disorders such as the obstructive sleep apnoea syndrome, periodic limb movement disorder and parasomnias cannot be ruled out without these additional parameters. The minimum montage for EEG recordings depends on the clinical problem and the scoring rules adopted. For the diagnosis of complex parasomnias and nocturnal epilepsy, more EEG and EMG recordings with synchronised video are necessary. The PSG study is typically done in a laboratory setting. During the study, the attending clinical staff observes sleep features and document the behaviour of the patient, either directly or via a computer screen that displays all the data.

#### **Appraisal of present attended laboratory PSG: 'The Gold Standard'**

Apart from providing an account of an individual's behavioural and physiological sleep patterns, the techniques used in assessing sleep disorders must endeavour not to modify the sleep features that they are designed to record; they must also be tolerable and acceptable to patients and must be economically viable.

Current practice for laboratory based PSG (LPSG), which is the gold standard for the assessment of sleep disorders, has several limitations, particularly with regards to assessing certain forms of sleep disorders such as parasomnias. Firstly, the unfamiliarity of the laboratory sleeping environment, the presence of laboratory personnel during the sleep period, and the common laboratory practice of scheduling of bedtimes and wake times may all systematically influence LPSG findings. There are, therefore, grounds to suspect that LPSG may not always provide data that are representative of patients' typical sleep patterns. LPSG often result in first-night effects (FNE), which are associated with an unnatural environment (Agnew, Webb, & Williams, 1966);(Lorenzo & Barbanoj, 2002). In addition, subject compliance may be impaired and naturalistic tendencies reduced if the subject must sleep in the laboratory. Until the development of more practical techniques

is achieved, sleep disorders of the general population can neither be fully described nor can the provision of routine scientific diagnosis for these conditions be realised.

Secondly, PSG recordings in the sleep laboratory yield several problems. An extensive laboratory study by Fisher and colleagues in 1970 showed that nightmares tend to occur less often and less intensely in laboratory setting (Fisher, Byrne, Edwards, & Kahn, 1970). Earlier studies had also shown that the artificial setting of the sleep laboratory may influence the contents of dreams; Domhoff and Kamiya (1964), for example, show that dreams recalled in the sleep laboratory were less charged with affect than dreams recalled at home (Domhoff & Kamiya, 1964). A more recent study comparing episodes occurring at home and in the laboratory confirmed these earlier studies by showing that motor episodes were as frequent and as long in the hospital as they were at home, but that complex behaviours such as sleep walking, prolonged episodes and dream enacting behaviours were mostly observed at home (Mwenge et al., 2013).

Thirdly, certain sleep disorders that occur sporadically may require several nights to capture and laboratory environments are usually less flexible, allowing only one to two nights of recording (Leo, 2003). Home studies would potentially allow for a longer recording.

Fourthly, overnight LPSGs require continuous monitoring by staff, which is a financially costly exercise in addition to the costs related to a hospital bed. The issues of cost and inconvenience have motivated the development of portable devices capable of evaluating sleep in the home (Kelly, Schwamm, & Bianchi, 2012). The expected labour-saving and cost-saving benefits of home recordings, as well as the possibly increased comfort, privacy and convenience, will make home recording the preferred method for many research and clinical applications (Ancoli-Israel, Kripke, Mason, & Messin, 1981).

And finally, the accuracy of documented behaviour is largely dependent on the observer, usually the sleep physiologist or attending nurse, and may be quite limited depending on

the observer's knowledge, experience and level of vigilance over the course of the night. Video recording can alleviate this limitation. For instance, video-PSG (VPSG) is often required to separate atypical nocturnal behaviours from nocturnal seizures, and to help identify when obstructive sleep apnoea or other sleep disorders are causing or contributing to frequent parasomnias or seizures (Kushida et al., 2005),

There is, therefore, grounds to hypothesise that representative sleep data and ecologically valid measurements require approaches to monitoring sleeping behaviour in the patient's own environment, rather than in the laboratory.

### **1.5 Portable home sleep studies**

A potential way of addressing these limitations is to take advantage of advances in technology to perform full PSG studies in the patient's home. Home recording would help to obtain a more natural sleep, potentially address the FNE of the laboratory studies (Agnew et al., 1966), and may be less costly (Ghegan, Angelos, Stonebraker, & Gillespie, 2006). Portable sleep study systems have been developed because of several recognised advantages over sleep-LPSG, including sleep in a more familiar and flexible environment, fewer monitor leads, more convenience for patients with transportation problems, probably less disrupted sleep, less technical complexity and lower costs, among other reasons. Various levels of home sleep studies have been defined, ranging from single devices such as pulse oximetry and actigraphy (Type 4 devices), to multichannel cardiorespiratory sleep studies for which a montage like PSG, with the exception of the neurophysiological channels, is applied (Type 3 devices), and is also referred to as polygraphy. Where parallel recordings have been made, results obtained by ambulatory home sleep systems have been shown to be generally in agreement with conventional PSG (Sewitch & Kupfer, 1985).

### **1.6 Appraisal of current portable home sleep studies**

The role of home current sleep studies, however, is still a matter of debate. There are controversies over their effectiveness; some studies suggest that home sleep studies are inferior in quality (Escourrou, Luriau, Rehel, Nédelcoux, & Lanoë, 2000); (Gagnadoux, Pelletier-Fleury, Philippe, Rakotonanahary, & Fleury, 2002) due to, among other things,

data loss, fewer channels, and a lack of behaviour monitoring. In a study by Ayappa, Norman, Seelall, and Rapoport (2008), as much as 14% of the sleep time data was lost. A crossover study comparing home-unattended PSG to nurse-attended PSG in a local hospital found that data was inadequate for interpretation in 23.4% of cases compared to 11.2% of attended studies (Gagnadoux et al., 2002). A randomised crossover trial comparing home unattended with hospital telemonitored PSG concluded that hospital telemonitored PSG is technically superior and preferred by the patients (Escourrou et al., 2000). Portier et al. (2000) also reported a failure rate of 20%. (McCall, Erwin, Edinger, Krystal, & Marsh, 1992) have highlighted the risk that data may be difficult to interpret because of uncorrected artefacts due to the lack of direct supervision by trained staff. Conversely, a European-wide study by Gagnadoux et al. (2002), looking at various aspects of ambulatory recording, found that not only did patients prefer ambulatory recording, but it was also less costly compared to the hospital setting. Kristo et al. (2001) suggested that, due to advances in technology, home PSG is feasible and cost effective; however, a review by Carlson (2008) refutes the claim that home PSG is cost-effective. Acoli-Israel et al. (1981) reported some minor reliability problems with the portable recordings appearing in their initial recordings, which they say improved as equipment became better.

These past studies highlight several issues. Firstly, there is the question of the failure rate and data quality. Secondly, the issue of patients' preferences is not adequately addressed. Thirdly, the cost implications for home-based sleep studies require clarity.

There are also other concerns with home recordings such as safety. Home video-PSG recording prevents the possibility of physiologists/physicians intervening during and after a parasomnia episode (Ingravallo et al., 2014); whereas, in a sleep laboratory such intervention would happen, and the intervention may also identify patients with other sleep events that could cause injury such as sleep walking, rapid-eye-movement sleep behaviour disorder and seizure episodes. Admittedly, patient safety has been a major focus in evaluating all advances of medicine (Henriksen, Battles, Keyes, & Grady, 2008). However, in sleep studies, an immediate response is often not critical and the very nature

of home sleep studies does not impinge on patients' behaviours in their natural environment. In general, portable PSGs are not necessarily unsafe, but the limited nature of the technology in these recording systems does not allow the identifying of sleep events that would be identified in a sleep LPSG and this a significant limitation. It is, therefore, befitting to state that although the home sleep study systems allow sleep disorders practice to greatly increase PSG productivity, they do not, in any way, replace the diagnostic LPSG. While home diagnosis portable devices can be used successfully in many patients, LPSG remains the diagnostic method of choice, either because of reimbursement policies or because of innate conservatism and a reluctance to abandon a perceived gold standard (Douglas, 2003).

Home sleep testing is currently targeted to sleep disordered breathing, and the data supporting the use of home sleep apnoea devices has been reviewed recently (Collop et al., 2011). The biased leaning of the current portable devices toward respiratory sleep disorders is a limiting factor as these home study devices are not suited for other equally deserving sleep disorders. This limitation calls for the continuing need to explore other ways in which home sleep studies can be adapted for other sleep disorders.

## **Chapter 2 Literature review**

### **2.1 Overview**

The introductory chapter has established the background, the complexity of sleep as a phenomenon, the diverse problems associated with sleep disturbances, the burden of sleep disturbances to the individual, family and society, and the need for correct and timely diagnosis. Current methods of assessing sleep disorders, and the disparity in terms of procedures and clinical utility between the laboratory and home sleep studies, have been discussed. This chapter will focus on a literature review of published work addressing comprehensive diagnostic techniques for sleep disorders in the home environment. The term home video telemetry polysomnography (HVTP) will be used to refer to these comprehensive diagnostic techniques. The term was chosen to capture pertinent descriptive and functional elements involved in this diagnostic technique. Home sleep studies reported in the literature will be reviewed to provide a knowledge base identifying gaps and limitations in the current literature and for the subsequent research question for this study.

The impact of new technologies, the effects of changing health economics and patient focused healthcare are some of the challenges that sleep medicine must face in the provision of sleep-related care services in the future as a medical specialty. Home video telemetry polysomnography, encompassing audio-visual signals and expanded neurophysiological and cardiorespiratory parameters recorded in the patient's home environment, is a promising novel method for the assessment of sleep disorders. However, the feasibility of such a model of sleep study is unclear regarding the data signal quality, patient acceptability and cost implications.

The purpose of this literature review is to evaluate the current state of knowledge on practice in sleep disorders assessment in the patients' home environment. The specific objectives of this literature review are threefold:

- (a) To describe the approach used to conduct this review and to describe the studies.
- (b) To assess the evidence in the literature concerning sleep disorders assessment and the limitations of current assessment methods regarding home based comprehensive sleep studies
- (c) To rationalise the proposed research on the feasibility of home video telemetry polysomnography model for assessing sleep disorders.

## **2.2 Literature search strategy**

To identify relevant articles, an electronic search strategy was run in Medline, CINHAL and Web of Science. These databases were chosen because they contain articles on a wide range of clinical areas. References on the articles retrieved were checked to provide a further source for relevant articles. The key search terms used were: sleep studies, polysomnography, PSG, video, home, ambulatory, portable, out of centre, unattended, remote, telehealth, telemedicine and unsupervised. The aim of searching with a wide range of terms was to capture all non-laboratory based PSG studies and/or sleep studies, mainly in the home or assisted residential, or other non-sleep laboratory settings. The subjects were restricted to humans. There was no gender restriction on gender or age. The search criterion was published literature available via electronic databases that focused on non-laboratory based studies published between 2007 and May 2016. The year 2007 was chosen as that was the year when a major review of non-laboratory based portable devices, previously described in 1994, was published by the AASM, depending on the number of channels and modalities recorded (Collop et al., 2007). Using the Medline database, the initial search was carried out using the key terms pertaining to sleep and sleep disorders assessments, i.e., 'sleep studies', 'polysomnography' and 'PSG'. These were combined with the Boolean operator 'OR' to ensure that all articles relating to studies of sleep disorders were included as the three terms can sometimes be used

interchangeably. Using the Boolean operator 'AND', the results of initial search were individually combined with the term 'video'. This allowed filtering to include only the studies that included video recording. The results were filtered further using terms that refer to sleep studies undertaken outside of the laboratory environment. These terms were home, ambulatory, portable, out of centre, unattended, remote, telehealth and telemedicine and unsupervised. The exercise was repeated using CINHAL and web science. The exercise produced a total of 259 articles (Table 4).

**Table 4 Search strategy results**

	Search Criteria	Medline	Web science	CINHAL	
#1	'sleep studies' OR 'Polysomnography' OR 'PSG' from October 2007-May 2016	28729	103,473	98,346	
#2	#1 AND 'Video'	582	1009	962	
#3	#2 AND 'home'	26	64	13	105
#4	#2 AND 'ambulatory'	13	18	20	51
#5	#2 AND 'portable'	7	16	10	33
#6	#2 AND 'out of centre'	2	5	4	11
#7	#2 AND 'unattended'	2	3	4	9
#8	#2 AND 'remote'	3	8	2	13

#9	#2 'AND 'telehealth'	4	2	2	8
#10	#2 AND 'telemedicine'	4	9	10	23
#11	#2 AND 'unsupervised'	2	2	2	6
		65	127	67	259

After duplicates, reviews, expert opinion articles and editorial commentaries were removed from the 259 articles identified from the literature search, 28 articles remained. The 28 studies were grouped in terms of the study type, indicating the parameters included in the study and how they fitted within the four categories of the AASM's classification of sleep studies (Table 5).

**Table 5 Reviewed articles by types of studies**

Study types and how they fit in the AASM's classification of sleep studies.	No of articles
Studies combining laboratory based video Polysomnography and home based Polysomnography. This setting can be considered as equivalent to Types 1 and 2 of the AASM's classification respectively)	16
Home video EEG telemetry - (No equivalent in AASM's classification)	1
Home video somnography -This may be considered as a form of type 4 sleep study in AASM's classification as it records only video	5

Home Polysomnography. This may be considered as Type 2 in AASM's classification)	3
Home Video Polysomnography. This setting has no extended montage. This has no equivalent in AASM's classification)	2
Home video EEG-Telemetry Polysomnography. This setting has extended montage. This setting would be ideal for parasomnia assessment. There is no equivalent in AASM's classification	1
	28

Apart from home video somnography, which is essentially a form of Type 4 sleep study since only video recording is done, and home polysomnography, which could be regarded as a standard Type 2 study consisting of neurophysiological channels for sleep staging and cardiorespiratory parameters, all other studies are variations of the Type 2 studies. Abstracts of these 28 papers were reviewed. Several publications reported studies that compared laboratory and home studies in the same patient groups. The studies in this group that did not have home video recording as one of the evaluated parameters were excluded from the current review, regardless of whether video was included in those recorded in the laboratory setting. This exercise reduced the number of articles further to 12. The full texts of these twelve articles were retrieved. These twelve articles were reviewed considering the following:

- i. The type of sleep disorder investigated,
- ii. The comprehensiveness in terms of recorded parameters reported,
- iii. The quality of the data obtained and how data quality was evaluated,
- iv. Acceptability of the procedure by patients,
- v. The cost implications.

- vi. Location of the study. Whether they were carried out in the patient's own environment or another out of centre environment such as a general ward or assisted home.

The results are summarised in Table 6

**Table 6 Summary showing the profile of parameters reported in different studies reviewed**

Author	Sleep disorder	Parameters reported	Acceptability	Cost	Location
Sitnick et al., 2008	Nocturnal awakenings	Actigraphy+Video	No	No	Home
Moore et al., 2011	Parasomnia	Video only	No	No	Home
Cuppens et al., 2012	Parasomnia	Video only	No	No	Outside lab
Mwenge et al., 2013	Parasomnia	Video only	No	No	Outside lab
Wang et al., 2014	OSA	Video only	No	No	Home
Grover et al., 2009	OSA	Cardiores+Telemonitoring	Yes	No	Lab+Nonlab
Coma-Del-Corral et al., 2013	OSA	Cardiores+Telemonitoring	No	Yes	Outside lab
Stepnowsky et al., 2007	OSA	Cardiores+Telemon	Yes	No	Lab +Home
Bruyneel et al, 2013	OSA	Video+Neuro+Cardioresp	Yes	Yes	Lab/Home
Kayyali et al., 2008	Sleep disturbance	Cardiores+Neuro+Video	No	No	Home
Brunnhuber et al., 2014	Seizure	Neuro+Video	Yes	Yes	Home
Chacko et al., 2014	Volunteer	Neuro+Video	No	Yes	Home

## **2.3 Findings and discussion**

### **2.3.1 Study types**

The literature review shows that the reviewed studies were methodologically varied. Of these twelve articles (Table 6), four were video only with no PSG parameters, four were video with limited PSG channels, and four were full PSG studies. Of the four studies that fulfilled the criteria of full PSG, two were telemonitored with synchronised video (Kayyali et al., 2008) and (Bruyneel, Van den Broecke, Libert, & Ninane, 2013), one was a 'proof of principal' study with synchronised video that was monitored by one of the investigator, who was also the subject (Chacko, McCullagh, 2014), and one was an unattended video EEG telemetry (VET) study (Brunnhuber, Amin, Nguyen, Goyal, & Richardson, 2014).

### **2.3.2 Quality of data reported**

The parameters recorded and data analyses reported in the studies reviewed were varied and difficult to compare. The terms used to report data quality used descriptive terms such as 'effective', 'useful' and 'satisfactory' without providing clear meaning of the terms or the methodology on how data was analysed. Those that performed analysis of data quality reported failure in 10% of recording (Bruyneel, Van den Broecke, Libert, & Ninane, 2013), no failure (Kayyali et al., 2008) and success of 79-100 % in EEG and video recording (Brunnhuber et al., 2014)

### **2.3.3 Sleep disorders investigated**

Regarding the type of sleep disorders investigated in the twelve studies reviewed, five addressed obstructive sleep apnoea, three addressed parasomnias, one addressed seizures, one study addressed sleep disturbance related to fibromyalgia, one addressed nocturnal awakenings and one was of a normal volunteer (Table 6). In a survey carried out by the British Sleep Society, 24 of 37 centres that responded were essentially concerned with respiratory sleep disorders (Stores & Wiggs, 1998). At present, there is a bias towards sleep apnoea in sleep medicine practice and, consequently, diagnostic procedures including practice standards are inclined towards the diagnosis of respiratory related sleep disorders. The focus on sleep apnoea as the defining condition of sleep medicine underestimates other sleep disorders, which equally affect good sleep. As the

impact and economic burden of non-respiratory sleep disorders become more and more apparent, this bias need to be re-addressed as the requirements to assess other sleep disorders continue to rise.

#### **2.3.4 Study location**

The locations where the studies reviewed were carried out were varied. Six of the twelve studies were performed at home in patients own environment, three studies were carried at home as part of laboratory-home comparative studies, two were performed outside sleep laboratories in other locations within a hospital setting and one was performed just outside sleep laboratory in an area adapted to resemble home environment as part of laboratory verses non- laboratory setting comparative study.

#### **2.3.5 Acceptability**

Of the 12 studies reviewed, four mentioned whether the home sleep studies were acceptable by the patients. There was little information on how acceptability was assessed and in eight of the studies reviewed, there was no mention of acceptability at all.

### **2.4 Discussion**

To effectively manage patients with sleep disorders and improve sleep health, underlying or comorbid conditions, which have profound implications for sleep, need to be considered. It is crucial that a gold standard recording system for sleep study is able to deal with all aspects of sleep to avoid unnecessary repeat studies. Such a recording system should be able to provide information on issues relating to normal sleep, parasomnias, sleep related breathing disorders, sleep related movement disorders, insomnia, behavioural sleep issues, narcolepsy, sleep and aging, circadian rhythm disorders, REM behaviour disorder, shift work disorder, etc. Sleep disorders, therefore, encompass a wide range of clinical scenarios with complex multifactorial interactions. The complicated multifactorial interactions that generate sleep disorders pose important challenges with respect to standardising diagnostic process. An adequate diagnostic procedure in sleep studies should be able to provide information on sleep itself, the

behaviour of the sleeping subject, and other physiological changes that may be tailored to address specific clinical problems. In view of the heterogeneity of sleep disorders, to find a single procedure to suit all clinical scenarios is a daunting undertaking. The procedure can be tailored to address a specific clinical problem. The reviewed studies did not demonstrate that this aspect has been fully addressed.

The AASM considers Type 1 laboratory based polysomnography (LPSG) to be the 'gold standard' method of evaluating sleep disturbances. Unattended Type 2 PSG, as defined by the AASM, would be equivalent to Type 1 but outside of the laboratory setting. However, the diagnostic value of unattended Type 2 monitoring is reduced by the inability to provide behavioural observations, or to attend to technical problems or make interventions during the night. In the laboratory setting, attending sleep physiologists or other trained staff observe the patient throughout the period of recording. In the absence of attending staff, the inclusion of synchronised video recording has been shown to provide vital behavioural information (Derry 2009). In addition to the inclusion of video, some studies were telemonitored to allow intervention by monitoring staff. According to Bruyneel et al. (2013), real-time attended HPSG through telematics data transmission is feasible and could be an important perspective in addressing the failure rate of home sleep studies.

The minimum number and type of parameters included in the standard recording remains an issue. The European guidelines (Pevernagie et al., 2006) and the AASM (Berry et al., 2012) differ in terms of the parameters that should be reported in standard PSG. Collop et al. (2011) have recently reviewed the classification of published types of sleep studies and suggested a new classification system based on measurements of sleep, cardiovascular, oximetry, position, effort and respiratory parameters (SCOPER) and detail the type of signals measured by these devices; however, the emphasis is on sleep apnoea. Jennum, and colleagues (2007) have suggested the expansion of standard PSG to allow assessments of disorders such as frontal lobe seizures that might present as parasomnias (Jennum, Santamaria, & Force, 2007). It appears from the literature that there is no single

type of PSG that can address all sleep disorders and that it would be more fruitful to tailor the procedure to a specific group of sleep disorders.

## **2.5 Summary**

In summary, even though the methodology of the articles reviewed was quite varied, the overall conclusions of the articles were consistent in that sleep studies performed outside the conventional laboratory setting are beneficial. There is considerable agreement as to the usefulness of home sleep studies. There are, however, several issues that require further consideration to make home studies more inclusive and diverse in evaluating sleep disorders. Firstly, the literature reviewed reveals that there is little information regarding assessing sleep problems in the home environment using PSG where neurophysiological, cardiorespiratory and audio-visual parameters are recorded simultaneously. Secondly, the available information shows that the current methods of assessing patients with sleep disorders in the home are limited in terms of parameters or recording channels monitored. For instance, in the twelve articles reviewed, four recorded video only. This means that although these studies could quantify behaviour features of the sleeping patients, they had no information on the correlation of physiological characteristics. Three of the twelve studies reviewed reported video EEG features without full polysomnographic channels and, hence, it is difficult to quantify sleep characteristics in these studies. Thirdly, there are hardly any studies reporting unattended comprehensive video telemetry polysomnography (VTP) as the reported studies are telemonitored studies necessitating a trained member of staff to be available to monitor the recording throughout the night from a distance. Fourthly, the cost implication of home sleep studies is lacking, although there is general agreement that home sleep studies would be cost effective (Bruyneel et al., 2013); (Chacko et al., 2014); (Grover & Cady, 2009). Of the twelve studies reviewed, only five studies mention cost; of these five, two studies provide details on how costing was carried out (Brunnhuber et al., 2014; Coma-Del-Corral et al., 2013). The other three make general statements, commenting that home studies are less expensive without providing details. Fifth, the

methods for assessing the quality of the recorded data are limited since the quality criteria is based on that developed by Redline et al. (1998) which is primarily for evaluating respiratory sleep related disorders. Finally, patient acceptability of home video telemetry polysomnography has not been widely addressed in the literature. Of the twelve studies reviewed, three studies reported that patients preferred to have the studies at home (Bruyneel et al., 2013) Grover & Cady, 2009); one study mentioned that patients preferred home without giving detail of how acceptability was evaluated (Stepnowsky, Palau, Marler, & Gifford, 2007). In eight of the studies reviewed, patient preference was not mentioned.

## **2.6 Need for a comprehensive home-based sleep studies**

In view of the limitations of the previous home studies, there is increasing interest in finding more efficient ways to provide comprehensive sleep study services that are economically viable and acceptable to patients. One way to achieve this is by taking advantage of advancing technologies. In their editorial comments, Schrijvers and Goodwin (2011) suggest that,

“Adoption of new technologies is a fast-moving area that cannot sit back and wait for the evidence as traditionally gathered. New methodologies and approaches are needed and this will only come to fruition through better cooperation between scientists, professionals, product developers, and policy-makers” (p2).

The clinical utility of digital PSG recording for patients with sleep disorders is increasing as technology has become more portable and efficient, and data storage is less cumbersome (Ziegler, 2010). Simpler PSG systems, where video recordings are synchronised with recordings of a limited number of physiological signals, have been proposed in the past for low-cost portable home sleep screening (Sivan et al., 1996). For a long time, there has been recognition that there is a place for special sleep studies systems, by which objective information about sleep patterns and physiological characteristics can be obtained from recordings taken at home or in other non-specialised settings and that the place for such evaluation may be appropriate and wide (Stores, 1994). These include sleeplessness of

one form or another and episodic disturbances of behaviour such as parasomnias (Mahowald & Rosen, 1990).

New technologies mean that more creative diagnostic, monitoring and treatment methods are emerging and that the birth of telehealth has heralded a different future for healthcare provision in the form of pervasive healthcare. Many of the same variables recorded in the laboratory can now be recorded using home-based PSG systems. Most full PSG systems synchronise digital video recorders with EEG signals to correlate patient behaviour with sleep abnormalities such as nocturnal seizure disorders. Synchronised digital video recording can yield clear audio-visual information of abnormal nocturnal breathing that is not detected with the use of standard PSG (Banno & Kryger, 2005).

Polysomnographic systems with synchronised digital video recording have been used to diagnose paediatric sleep breathing disorders in the laboratory (Banno & Kryger, 2005). Diagnosis can be greatly enhanced by documenting suspected non-respiratory related nocturnal behaviours with thorough clinical assessment during split-screen video-analysis. Laboratory based video polysomnography recordings have been used to correlate Polysomnographic signals with patients' sleeping behaviour, and respiratory and body movements in sleep (Banno & Kryger, 2005); (Silvestri et al., 2009). Combining the monitoring of video, PSG and other physiological parameters at home may allow for longer recording periods and minimise bias from monitoring in a sleep laboratory setting. Patients can sleep in their own environment, thus, providing opportunity for clinicians to gain information about how the individual sleeps in their typical sleep environment. There is also the likelihood that home monitoring could be a more cost-effective alternative to conventional laboratory based PSG.

Video EEG telemetry recording systems, widely available in long term epilepsy monitoring units in hospital settings, utilise a full complement of scalp 10-20 system electrodes with split video recording that can be adapted for complex video polysomnographic recording

for home recording. In adapting these telemetry systems to sleep studies in home environments, behaviours can be recorded with time-synchronised audio and video cameras. The audio-visual data can be further synchronised with neurophysiology and cardiorespiratory data to provide a complete tri-modal video PSG with the three modalities (audio-visual, neurophysiology and cardiorespiratory) necessary to assess patients with parasomnias. This tri-modal set up can be applied to record simultaneously in a home environment.

One way of achieving this is by applying store and forward or store and retrieve methods to home sleep studies. Store and forward refers to the concept that digital images of a patient, for rendering a medical opinion or diagnosis, can be stored and electronically transmitted to a central station away from the recording site. Sometimes, the data does not traverse any distance, but simply remains on a server to be retrieved later. This is referred to as store and retrieve. This store and retrieve telehealth model of pervasive health is what this feasibility study adopted for the HVTP. This form of sleep study is particularly suited to sleep disorders such as parasomnias where clinical manifestations are discrete events with major behavioural components. The present study is an exploration of the feasibility of such a method of sleep study for patients undergoing assessment for parasomnia.

The aims of the study are:

- i. To carry out HVTP recordings and examine the quality of data in terms of readability to answer the following question: Can home video telemetry polysomnography be performed successfully for clinical utility in patients referred for sleep studies to assess parasomnias?
- ii. To explore using one-to-one semi-structured interviews, the patients' views, and their experiences of having HVTP performed in their own homes to determine its acceptability.
- iii. To examine the cost aspects of performing HVTP by identifying various cost related elements to answer the following question: What is the average cost of

carrying out HVTP in patients undergoing assessment parasomnias living within a defined geographic catchment area?

## **Chapter 3 General Methods**

### **3.1 Overview of the general methods**

In Chapter 2, a comprehensive HVTP recording model was proposed as a viable method of assessing sleep disorders, especially parasomnias, in the home environment. Sleep studies, including the proposed model, are expected to provide information on the patients' sleep and behavioural characteristics. The accuracy of characterisation of behavioural and sleep features is dependent on the quality of physiological data collected during the sleep study. However, both the data obtained and the degree to which that data can adequately be used for electro-clinical characterisation of the sleeping subject is influenced by many factors including the environment (Iber et al., 2004), and the nature and number of parameters recorded (Jennum et al., 2007). Current advances in technology raise the possibility of not only being able to move sleep studies from laboratories to patients' homes, but also expanding the parameters recorded by current traditional PSG. This expanded PSG has been referred to in this study as Trimodal HVTP, which consists of three main modalities or parameters:

- i. Neurophysiological,
- ii. Cardiorespiratory,
- iii. Audio-visual.

However, the complexity of carrying out HVTP as a clinical diagnostic procedure presents several practical and methodological difficulties that cast doubts on its feasibility. First, there is a need to accurately monitor and quantify various movements and physiological parameters simultaneously to relate patient behaviour with these physiological parameters. Second, it is a labour-intensive and expensive procedure. Third, there are logistical difficulties associated with performing these complex procedures in patients' homes.

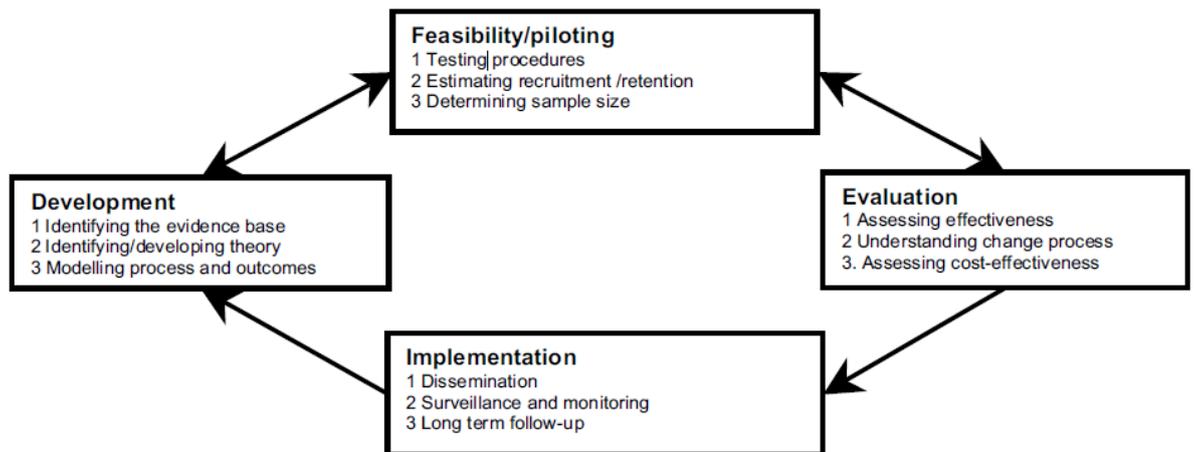
### **3.2 Approach**

The various interacting components associated with this proposed HVTP fits the criteria outlined by Craig et al. (2013) for a complex intervention. In a complex interventional system with various interrelated components, it is important to understand how parts of the system interact and whether the intervention works in everyday practice. The fundamental concepts defined by Cochrane (1972) in addressing complex interventions concern whether the intervention can be done (i.e., is it efficacious?), whether it works (i.e., is it effective?), and whether it is worth it (i.e., is it efficient?). These three elementary questions lay the foundation for addressing the question of whether HVTP is feasible as a potential diagnostic clinical procedure in sleep medicine. The purpose of this project, therefore, is to explore the feasibility of HVTP as a potential method for patients undergoing assessment for parasomnias by ascertaining whether the procedure can be carried out successfully in their homes. Success in this context requires addressing the following three distinct aspects:

- i. First, it is critical to ascertain that the quality of HVTP signals recorded in the process is sufficient to allow clinical practitioners to quantify both the physiological and behavioural characteristics of the sleeping patient;
- ii. Second, it needs to show that the procedure is acceptable to the patients;
- iii. Third, that the costs involved are not so great that they render the intervention unsustainable.

### **3.3 Research plan**

By adopting the model suggested by the Medical Research Council (Craig et al., 2013), a feasibility study would be suited to address the initial aspects of this complex HVTP recording strategy. In adopting this model, feasibility studies are intended to determine whether an intervention is appropriate for further testing (Figure 3). They enable researchers to assess whether the ideas and findings obtained can be shaped further to be relevant and sustainable. They are pieces of research done before a main study to estimate important parameters that are needed to design the main study.



**Figure 3 Complex intervention stages adapted from Craig et al. (2013)**

The primary focus in this study is to measure and analyse the HVTP physiological and audio-visual data to provide pertinent information that can be used to tailor a larger study of the effectiveness of HVTP as a diagnostic procedure. During this feasibility study, the data obtained will be evaluated for clinical utility and, where applicable, it will be used for clinical decisions; it will, therefore, negate the need for further laboratory testing for the individual patient. Where the obtained data is deemed insufficient for clinical decision, arrangements will be made for standard laboratory testing for the patient.

To address the various components of this study, a mixed method methodology was adopted with three strands:

- i. The traditional PSG quantitative method with expanded EEG/EMG channels and synchronised audio-visual recording was used to examine the sleep characteristics to answer the following question: Can HVTP be performed successfully for clinical utility in patients undergoing assessment for a potential parasomnia sleep disorder within their home environment?

- ii. A qualitative element exploring aspects of patients' acceptance of such a procedure was used to provide the basis for identifying those areas that are important to the patients in relation to the HVTP procedure.
- iii. Quantitative cost elements were derived from micro costing analysis of materials and activities associated with carrying out the HVTP procedure in the patients' homes to answer the following question: What are the main cost elements involved in successfully carrying out HVTP in patients being assessed for potential parasomnia sleep disorders living within a defined geographic catchment area.

### **3.4 Research design**

Mixed methods research generally refers to the processes of collecting and analysing both qualitative and quantitative data in a single research project (Driscoll, Appiah-Yeboah, Salib, & Rupert, 2007); (Jogulu & Pansiri, 2011) by combining qualitative and quantitative research traditions in a single research enquiry (Moreno-López et al., 2011). Mixed method designs can provide pragmatic advantages when exploring complex research questions (Homer et al., 2008) (Nutting et al., 2009) due to their flexibility in combining different but related outcome measures in the same study. The philosophical assumption in using mixed methods is that the use of quantitative and qualitative approaches in combination will provide a better understanding of the feasibility of HVTP as a potential method of assessing patients with sleep disorders than either approach alone. Although the three strands of this mixed method study address different research questions, the three different component parts combine in a complementary way to create a comprehensive understanding and to achieve a single, unified outcome (Bazeley & Kemp, 2012). For instance, the data obtained may be readily readable, but patients might find it unacceptable to have the procedure carried out in their own homes. Equally, patients might find the process acceptable and data quality might be of high quality, but the cost may be so high that is not sustainable.

Mixed methods can be either fixed or emergent (Lochmiller & Lester, 2016). Fixed mixed method designs are mixed method studies where the use of quantitative and qualitative methods is predetermined and planned at the start of the research process, and the procedures are implemented as planned; emergent mixed method designs are found in studies where the use of mixed methods arises due to issues that develop during the process of conducting the research. For this study, it was important to decide whether fixed mixed or emergent mixed method was appropriate. Due to the resources, available for the study, the time constraints allowed for the study, and the multiple parameters to be measured during the HVTP process, a fixed mixed method approach with three strands was implemented for this feasibility study. Two of these strands, dealing with HVTP and cost data, were quantitative; the third, dealing with patients' acceptance of the procedure, was qualitative. Data collection was concurrent for the three strands in the same group of patients. The three strands were expected to address different aspects of the primary research question with the HVTP data quality having priority. Quantitative and qualitative data were considered individually and in relation to the other two strands to help draw conclusions during the overall interpretation at the end of the study; specifically, it was used to determine whether home video telemetry polysomnography is technically feasible, financially viable and acceptable to patients in order to potentially be applicable for clinical utility.

### **3.5 Ethics**

The study was reviewed and approved by King's College Hospital Neuroscience Advisory group. It was further reviewed and given favourable opinion by the National Health Service NRES Committee under reference number 14/LO/0457. As the organisation, responsible for conducting the research, King's College Hospital research and development committee reviewed and approved the study, taking responsibility for sponsorship as the research site for the study under registration number KCH14-121 (Appendices 5 and 6)

## **3.6 Participants**

### **3.6.1 Participants' characteristics**

The study site was based at King's College Hospital, London. The hospital provides local services primarily for people living in south-east London, providing not only acute services to the inner city, but also serving as a tertiary referral centre for certain specialties to millions of people in southern England. Neurological and sleep disorders are among these specialties. The Video EEG Telemetry (VET) unit at King's performs about 450-500 VET procedures in a year for the evaluation of neurological disorders. About 10-15% of these are patients referred for neurological related sleep disorders requiring Video Telemetry Polysomnography (VTP) studies, with parasomnias forming the largest part of this subgroup. In this study, referrals received for VET were screened to identify those requiring VTP studies for assessment of parasomnia. The targets were all patients with a history suggestive of parasomnia. Those patients who presented with a history of events of an unclear nature occurring at night requiring clarification as to whether they were epileptic or if they were sleep related were also included. The subjects were male or female adults (18 years or over). For practical reasons, and in keeping with the current practice of outreach services for the unit, only those living within a radius of 40 miles from King's College Hospital were included, which is generally the catchment area covered by the unit. It was also required that the home environment of the potential participants could be adapted to accommodate the recording equipment.

Sleep study patients requiring other tests after PSG studies, such as the multiple sleep latency test, and those requiring half a night for a treatment trial, e.g., with continuous positive air pressure, as part of the PSG were excluded, as the equipment set up for this study was not capable of performing these studies at home. In addition, both these procedures require the intervention of trained members of staff.

Those patients living with family members or house mates who objected to appearing on the video recording having read the information provided were excluded from the study as the investigator could not guarantee that the video aspect of the recording would only

capture the patient. Those that changed their mind and withdrew after giving their initial consent were also excluded and were put back on the waiting list for standard LPSG. With the approval of the National Research Ethics Service (NRES) Committee, those who declined or withdrew after giving initial consent were granted the opportunity to voluntarily provide the reasons for declining or withdrawing as this information was considered relevant to the feasibility of the study by informing the design of the future main study.

### **3.6.2 Recruiting processes**

The sampling technique was consecutive sampling. The consecutive sampling was to help ensure that all those available and qualified to be included were serially entered into the study.

The consultant neurophysiologist screened referrals received for video telemetry to identify those that required PSG studies for assessment of parasomnia. The HVTP coordinator, who normally deals with administrative aspects of video telemetry initially contacted potential patients who were identified by screening. At this stage, they were informed about the hospital telemetry sleep study service and the possibility of undertaking home telemetry sleep study. It was explained to the patients at this point that the home sleep study service was currently undertaking a research project, and if they were interested the person carrying out the research would get in touch with further details. If they said no to the study at this stage, no further action was taken regarding the study and they were processed normally for standard hospital based PSG.

The researcher then sent an information pack to those who expressed interest inviting them to take part in the study. The information pack was designed with the help of members of the Restless Leg Society, United Kingdom (RLS-UK), who reviewed, commentated and made suggestions that allowed the researcher to appreciate the important issues to include in the pack from the stakeholders' point of view. The information pack consisted of information sheets and consent forms for the patient and their partner or roommate (Appendices 1, 2 ,3 and 4).

Potential participants were requested to respond within two weeks by phone or post. Those who agreed to participate were further contacted via telephone, and a home video telemetry assessment questionnaire was carried out to establish the suitability of the environment using our home studies protocol for telemetry. The aim of this assessment was to establish the environmental basics such as accessibility, room layout, potential safety risks to staff and equipment, electricity supply and sockets accessibility, type of pets, if any, and if they posed any eminent danger to equipment or staff, etc. The researcher contacted those deemed suitable for the home study that fulfilled both the inclusion criteria above and the environmental criteria; they were then offered the opportunity to ask for further clarification about the study and to go through the consent form. They were also offered an opportunity to meet the researcher in the hospital setting before the first home visit, but no one took up this offer. If they were happy to proceed, an appointment was made. Informed consent was obtained from the patient involved and from partner or spouses as required. In addition to the already provided patient information, the researcher re-explained to patients the purpose of the research, how they were invited, and the voluntary nature of their participation. Those who declined to participate, or were deemed unsuitable due to environmental considerations, were placed on the telemetry waiting list for a laboratory based sleep studies appointment.

### **3.6.3 Privacy and safety considerations**

Videography is, in practice, an integral part of HVTP. With respect to ensuring participants' protection in the context of videography, the primary ethical issues included informed consent, confidentiality and privacy, and participant burden and safety (Broyles, Tate, & Happ, 2008). During HVTP, documenting aberrant nocturnal behaviours is clearly a necessary requirement. However, this process of documentation raises issues surrounding patients' privacy. Privacy issues, in turn, raise concerns about the potential for subsequent patient anxiety. To alleviate such anxiety, strategies for respecting patient modesty were addressed with individual patients. They were reassured by providing them with online feedback about what was being recorded. They were also advised that when/if videotaping interfered with their routines or privacy, they could redirect the

camera as necessary or, if they wished, they could use a piece of cloth to completely cover the camera lens. They were also made aware that although this measure was helpful for the picture recording, sound recording continued in the background.

### **3.6.4 Safety consideration of the researcher**

Setting up sleep studies in the patients' homes carries safety concerns associated with lone workers. In addition to risk assessments and relevant training for lone workers by King's College Hospital, the researcher carried a protective device (Figure 4) linked to a central station. When activated, staff at the central station could overhear conversations between the researcher and other people and act accordingly. In addition, throughout the period of the visit, the driver accompanying the researcher always stayed outside the house and could be called by phone to help if needed.



**Figure 4 Reliance lone worker protection device carried by researcher as name badge**

### **3.6.5 Sample size determination**

For pilot and feasibility trials, while a sample size justification is important, a formal sample size calculation may not be appropriate (Billingham, Whitehead, & Julious, 2013). A pilot sample size is, instead, based on the pragmatics of recruitment and the necessities for examining feasibility (; Leon, Davis, & Kraemer, 2011). Recommendations in the literature are variable. For example, Hertzog (2008) recommends between 10-40, depending on the type of study. Julious (2005) recommends a minimum of 12 subjects

per group and a sample of 30 has been recommended as a rule of thumb for feasibility studies (Browne, 1995).

For the present feasibility study, in consultation with a statistician at King’s College London, and in the light of the referral pattern of patients to the telemetry unit at King’s College Hospital, a sample of 30 participants was suggested as feasible for the study. The Program Evaluation and Review Technique three-point estimate (Kwak & Jones, 1978) was carried out to estimate the number that could realistically be collected in 15 months, which was the time period assigned to the study based on 450-500 referrals per year, of which about 10-15% are sleep studies.

Using the best, likely and worst recruitment scenarios of three, two and one participants per month, the three-point estimate calculation worked out to be 30 patients (Table 7).

**Table 7 Three-point estimate to work out the possible number of subjects for the study**

Three-point estimate	Per month
o=the optimistic estimate	3
m= the most likely estimate	2
p= the pessimistic estimate	1
Formula: $E=(o+4m+p)/6$	$(3+8+1)/6=2$
	2pts x 15 months= 30

### 3.6.6 Procedure

The participants underwent continuous HVTP monitoring for two days to include two nights. The researcher visited them daily to retrieve the recorded data and check that the recording was going well. Qualitative interview was performed in two parts. The first interview was conducted on the first day and the second interview on the last day. The cost related data was collected continuously by documenting every activity associated

with HVTP. Further details of the procedures associated with each part of the research are given in the following chapters.

## Chapter 4: Home Video Telemetry Polysomnography (HVTP) data quality assessment

### 4.1. Overview of data collection

The signals for the HVTP data quality strand of this mixed method projects were collected on two consecutive nights. The recording system comprised of components for recording multiple types of signals, reflecting different aspects of the HVTP. The signals were functionally grouped into three different categories: neurophysiological, cardiorespiratory and audio-visual. Different combinations of these groups of signals in a single synchronised recording can allow the procedure to be tailored to answer specific clinical questions (Figure 5). These are outlined below.

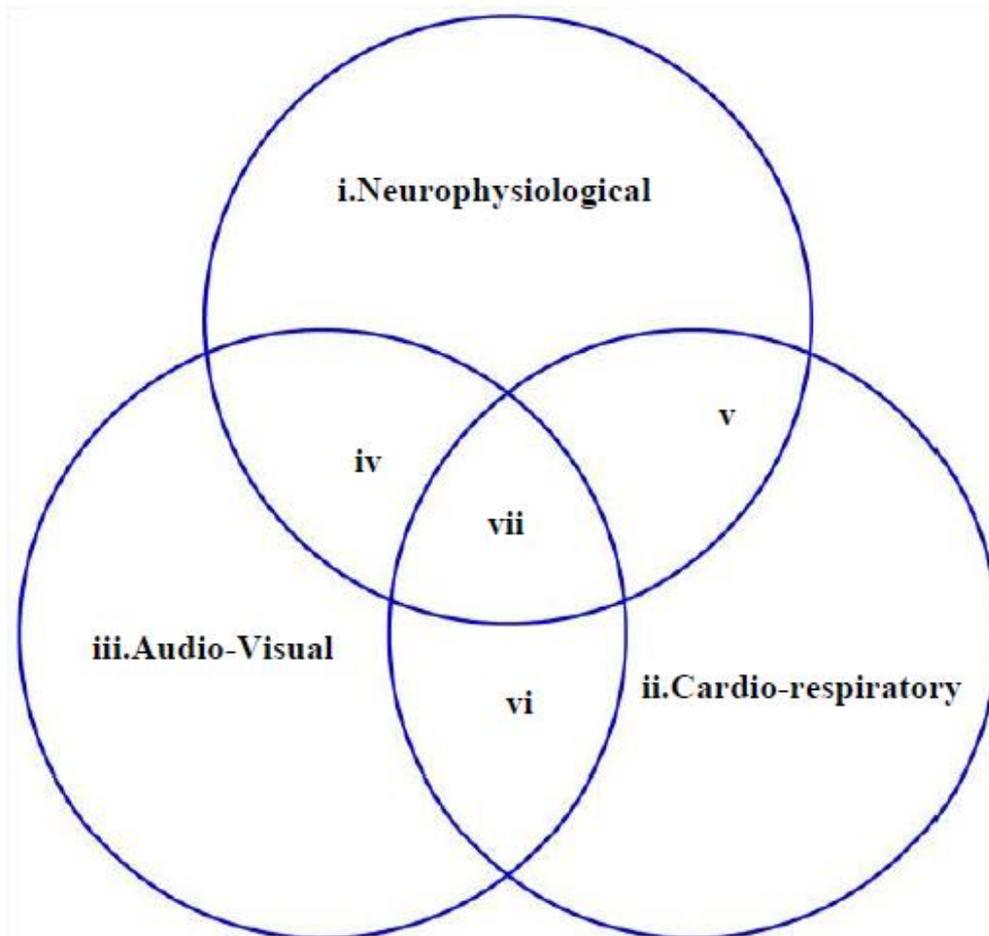


Figure 5 Functional components of recording strategies

- i. This is the routine EEG used in neurophysiology departments for assessment of patients with epilepsy. When sleep parameters are added, it can be used for assessing some forms of sleep disorders such as sleep apnoea and periodic limb movements in sleep (Bubrick, Yazdani, & Pavlova, 2014; Karakis et al., 2012);
- ii. Recommendation for cardiorespiratory - equivalent to Type 3 sleep study- with limited cardio-respiratory channels and no sleep staging channels (Collop et al., 2011); .Generally used for sleep apnoea.
- iii. Audio-visual can be useful for screening and characterising behaviour in sleep, but it is limited (Ipsiroglu et al., 2015; Sivan et al., 1996);
- iv. Neurophysiological with video: Current video telemetry for neurological disorders when full scalp EEG electrodes are applied. This combination is mostly used in VET units for assessment of epileptic disorders (Yis, Kurul, Oztura, Ecevit, & Dirik, 2013));
- v. Current gold standard PSG combining neurophysiological and cardiorespiratory signal (Togeiro & Smith, 2005; Van de Water, Holmes, & Hurley, 2011). This gold standard does not have audio-visual signals as a requirement although often included in the laboratory settings.
- vi. Cardiorespiratory with video: useful in diagnosis of some forms of sleep disorders but does not provide information on the actual sleep physiology features as sleep scoring channels are not included (Banno & Kryger, 2005; Dyken, Lin-Dyken, & Yamada, 1997; Liao et al., 2008); Liao et al., 2008);
- vii. This set up includes audio-visual signals, cardiorespiratory and neurophysiological channels with extended EEG-EMG channels. This set can be used for assessing neurological and respiratory disorders (Bubrick et al., 2014; Jennum et al., 2007). This set up can be tailored to be tried in patients' homes for parasomnia disorders assessment. At present, this tri-model set consisting of three modalities, i.e., audio-visual, cardiorespiratory and neurophysiological signals recorded

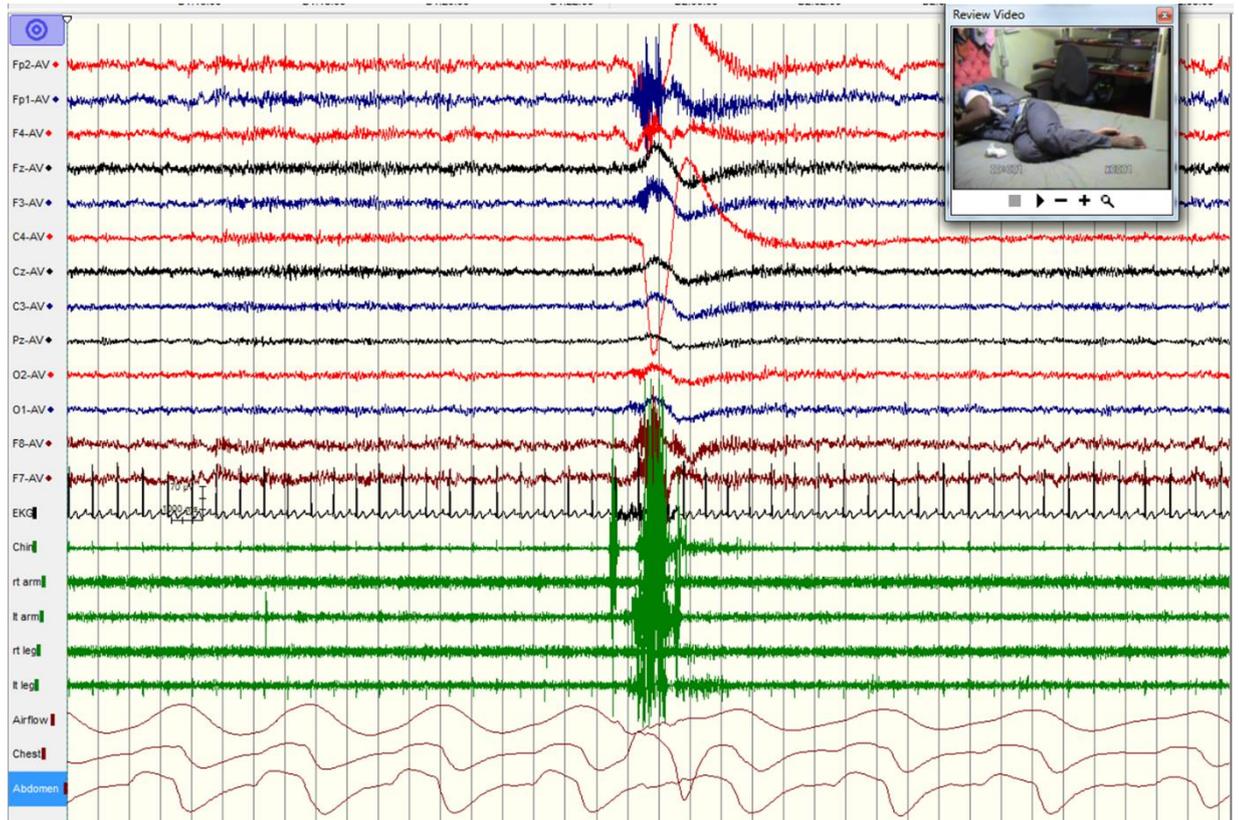
simultaneously with expanded montage is not in use for sleep studies in unattended home environments. In the present feasibility study, this set up was used and referred to as Home Video Telemetry Polysomnography (HVTP).

## **4.2. Materials and methods**

The materials required for collection of the HVTP data were grouped broadly into capital equipment, transport and consumables.

### **4.2.1. Capital Equipment**

The capital equipment consisted of modified hospital Video EEG telemetry recording system to form a video EEG-PSG recording system with the relevant software used to acquire, store and assist in the analysis of the sleep study. The various components of this prototype system were assembled and maintained with the help of an in-house equipment development engineer from the neurophysiology unit at King's College Hospital. For safety purposes, each individual component was checked to ensure compliance with European safety standards and that each piece of equipment connected to the patient had isolated circuit facility. In addition, all components of the recording system involved were checked to ensure they were of a safe weight to carry, in compliance with the health and safety requirements of safe weight for lifting (HSE, 2012). As the researcher involved in this study, I undertook to comply with the relevant guidelines and practices regarding lifting techniques and was appropriately trained in accordance with King's College Hospital's manual handling policy. Individual components were de-assembled and packaged in suitcases for transportation. These were re-assembled at the patient's home. The main components included a trolley, Nicolet 44 or 64-channel amplifier, laptop or desktop computer system, video camera and the associated connecting cables. The camera was mounted on a stationary tripod that was positioned on one side of the trolley. A laptop system was also used on some occasions instead of the desktop computer. Audio and digital video recording was synchronised with the other PSG to provide split video EEG-PSG online during recording and on review during analysis (Figure 6).



**Figure 6 Example of HVTP recording showing video, neurophysiological and cardiorespiratory parameters.**

In order to ascertain the fidelity of the recording system, instrumental calibrations were carried out before and after the study. Using calibration functions integrated in the recording system, a 50  $\mu$ v square wave signal for an epoch of 30 seconds at 10 mm/sec was passed through all channels. The resulting waveforms were inspected for uniformity, in terms of the general morphology of the output, particularly with regard to amplitudes, polarity, rise and fall times, etc. The audiovisual check was carried out by making a brief recording and then playing back. For sound, a one-minute recording was carried out and then listened to on playback to ascertain that the sound was clear and that words could be discriminated in an ordinary conversation. The picture was checked for the ability of an observer to discriminate eye blinks when the recording was carried out at a distance of about two to three metres.

#### **4.2.2 Consumables**

The consumables consisted mostly of the single use items that were used and disposed of after use. These included electrodes, conductive paste, skin preparation paste, adhesive tape, adhesive glue, quality tip sticks, bandages, acetone and olive oil, etc. (Figure 7)



Figure 7 Assembly of the consumables for setting up HVT recording

1. Micropore tape
2. Acetone
3. Net last bandage
4. Hypafix
5. Collodion tubes
6. Electrodes
7. Q-tip sticks (quality tip sticks)
8. Chino-graphs
9. Nuprep
10. Gauze
11. Ten20 Electrode gel
12. Cotton balls
13. Tape measure
14. Scissors
15. Olive oil
16. Comb
17. Surgifix net last

#### **4.2.3 Transport**

The hospital transport (van and driver) assigned to the neurophysiology unit at King's College Hospital was available for the project throughout the research period.

#### **4.3 Procedure for equipment assembly and patient set up**

After visual inspection of the environment, discussion with the patient and equipment lay out was agreed upon, the process of patient set up was initiated. Various components of the recording system were assembled together and the system was located at the convenient place within the recording area (Figure 8).



**Figure 8 Assembled recording system consisting of a laptop, mounted camera and recording device**

Electrode hook-up was carried out by the bedroom area with the patient seated on a suitable chair or on the edge of the bed. Some patients preferred the set-up of electrode application to be carried out in the kitchen area; in which case, a kitchen or dining chair was used. To protect and maintain the cleanliness of the surface areas where the consumables were laid, cloth, paper towels or other covering material such as towels were used cover the respective surfaces. The HVTP equipment trolley was used to lay out

the required set of supplies when electrode application was carried out in the recording area.

The HVTP system was designed to record multiple parameters (Table 8) to quantify physiological and behavioural characteristics during the sleep period according the proposed tri-modal system. The physiological parameters were grouped into as neurophysiological and cardiorespiratory consisting of 30 channels. These were synchronised with an audio-visual channel (Figure 6)

**Table 8 HVTP recording parameters and settings**

No Channels	Parameters	Sensitivity	HFF	LFF	Sample Rate	Electrode System	Reference
19	EEG	70uV/mm	70	0.5	>200	Maudsley	(Kushida et al., 2005);
2	EOG	70uV/mm	70	0.5	>200	AASM modified	
1	ECG	700uV/mm	70	0.5	>200	Shoulders	(Jennum et al., 2007);  (Frauscher et al., 2008)
1	Chin (1 & 2)	Variable	100	10	>200	AASM	
2	Bilateral FDS	Variable	100	10	>200	SINBAR	
2	Bilateral TA	Variable	100	10	>200	WASM	
1	Airflow		15	0.1	>25	AASM	The minimum channels required if sleep
2	Chest & Abdomen		15	0.1	>25	AASM	
1	Oximetry		-	-	>20	AASM	
1	Position		-	-	>1	AASM	

1	Snore		-	-	>200	AASM	apnoea or upper-airway resistance syndrome is also suspected (Kushida et al., 2005)
	Audio-visual	This was displayed continuously in the screen					

In the present set up, electrodes positions labelled F8/F7 in the international EEG electrode positions (Jasper, 1958) were used to record EOG signals and electrode positions labelled A2/A1 which are normally earlobe positions were located over the mastoid areas. The impedences for EEG/EOG/EMG were below 5 Kilo Ohms in all electrodes.

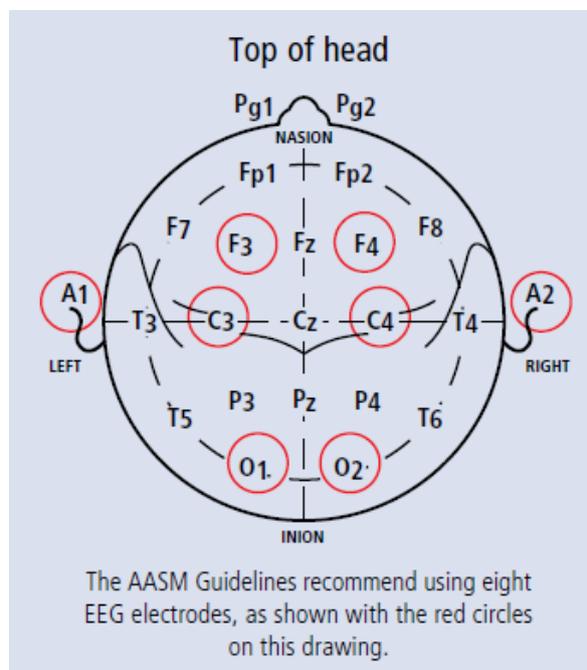
#### 4.3.1 Neurophysiological parameters

The recommended three derivations for EEG, two for EOG, and one of chin electromyogram (cEMG) (Silber et al., 2007) were applied for sleep staging. Additional EEG and EMG channels obtained other sleep related neurophysiological signals such as epileptiform discharges or axial muscle activity quantification. The extra EEG and EMG electrodes for extended montage consisted of a full complement of scalp EEG electrodes and the extra EMG channels consisting of bilateral tibialis anterior and bilateral flexor digitorum superficialis muscles (Bubrick et al., 2014; Frauscher et al., 2008).

#### Electroencephalogram (EEG)

The EEG is the primary parameter used in determining sleep stage. The role of the EEG in determining the sleep stage depends on the accurate recognition of specific EEG features. The accurate assessment of these electrical fields requires the appropriate placement of

electrodes and correct linking to the recording device. In this study, EEG electrode placement was applied using the modified Maudsley electrode system (Margerison, Binnie, & McCaul, 1970), which slightly deviated from the International ten twenty system (Jasper, 1958). The choice of a Maudsley system as opposed to the ten-twenty system was to comply with the practice at King’s College hospital, as it is considered to provide more coverage of scalp convexity compared to the ten-twenty system (Margerison, Binnie, & McCaul, 1970). A full set of scalp electrodes were applied including the AASM’s (Silber et al., 2007) recommended sleep staging electrodes, which are circled in the diagram (Figure 9). Unimed disposable electrodes were used. These were attached to the scalp with Hypafix tape and collodion using Ten20 conductive paste. To achieve and maintain electrode contact impedance of less than 5 Kilo Ohms for optimum recording, Nuprep was used to gently rub the area of electrode contact. Attention to detail in electrode application and signal acquisition was necessary to ensure the reliability and the accuracy of sleep staging.

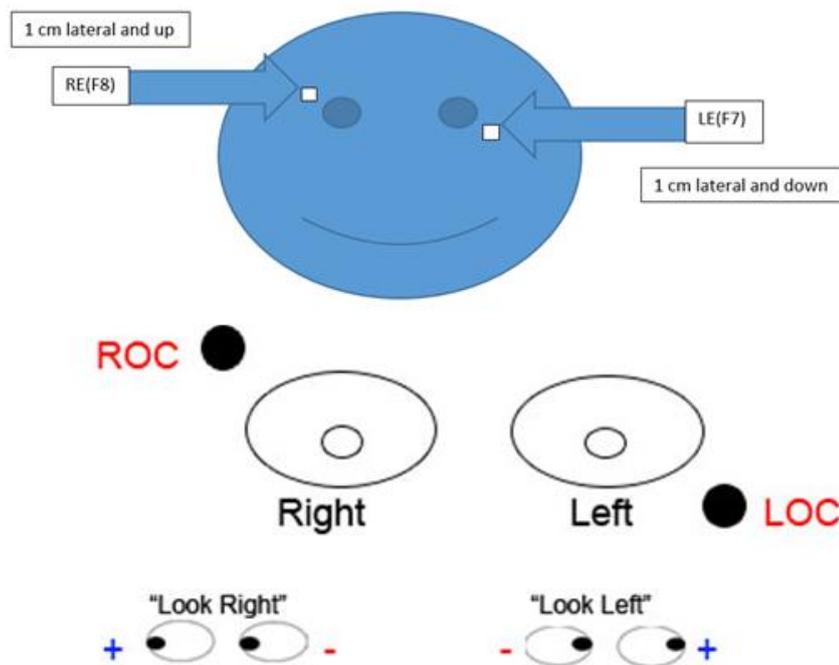


**Figure 9 Recommended electrodes for sleep recording (AASM, 2007)**

For the EEG signals, the settings were a sensitivity of 7  $\mu\text{V}/\text{mm}$ , a filter range of 0.5-70 Hz, and a sampling rate of not less than 254. The mains interference filter was left off unless environmental noise was insurmountable. Online EEG data acquisition was referential with an option of re-montaging during review.

### Electrooculogram (EOG)

The eye is a unique electric dipole with a strong relative positive charge on the cornea and a minor negative charge at the retina.



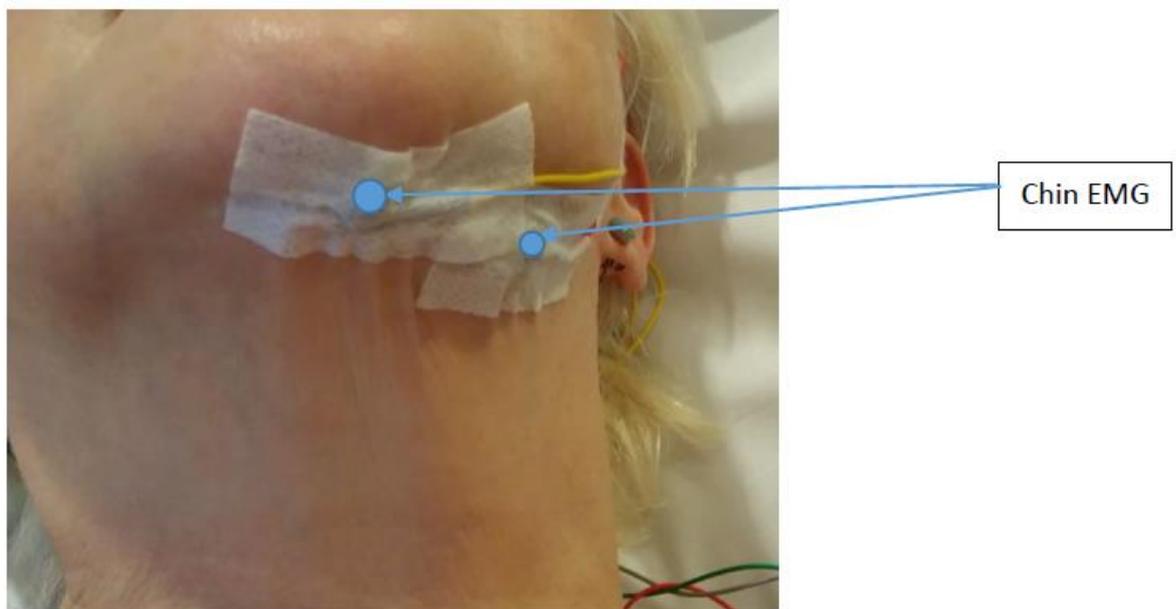
**Figure 10 EOG electrode positions- electrodes labels F8 and F7 were used**

During sleep, there are, among other phenomena, periodic episodes of increased oculomotor activity. For instance, the eye position changes slowly during drowsiness and rapidly during REM sleep. These eye movements create a potential field that can be detected by electrodes within the vicinity of the eye's potential field.

To record these changes for the study, two Unimed electrodes were used. The electrode on the right eye was placed about 1 cm lateral to the right outer canthus and 1 cm above. The electrode on the left eye was placed about 1 cm lateral to the left outer canthus and 1 cm below (Figure 10). Hypafix adhesive tape with a small amount of collodion was used with Ten20 electrode paste. This electrode configuration provided straightforward detection and identification of vertical and lateral eye movements as waveforms. Sensitivity, filter and sampling rate was the same as for the EEG channels.

### **Chin Electromyogram (cEMG)**

Electromyography measures the electrical potentials generated by muscle activity. Muscle tone diminishes gradually with depth of sleep, virtually disappearing during REM sleep. The role of cEMG is to help distinguish the waking state from sleep. Chin muscle activity generates the electrical fields caused by the membrane depolarisation of submental muscle fibres. This potential can be recorded with electrodes placed at the belly of the submental muscles. For this study, sleep staging EMG (sEEG) electrodes were placed over digastric chin muscles, 1-2 cm below the inferior edge of the mandible and 2-3 cm to the right or left of the midline (Figure 11).



**Figure 11 Chin EMG for sleep scoring**

Additional surface EMG electrodes were bilaterally placed over the tibialis anterior (TA) in the lower limbs and the flexor digitorum superficialis muscles in the upper limbs (Figure 12). Unimed disposable electrodes were used. They were attached to the skin using Hypafix tape with collodion and Ten20 conductive paste. The skin resistance was lowered by gentle rubbing with Nuprep to achieve impedance of below 5 Kilo Ohms. The instrumental setting was 5  $\mu\text{V}/\text{mm}$  for sensitivity, filters setting of 10-100 Hz and sampling rate of 254 samples per second.



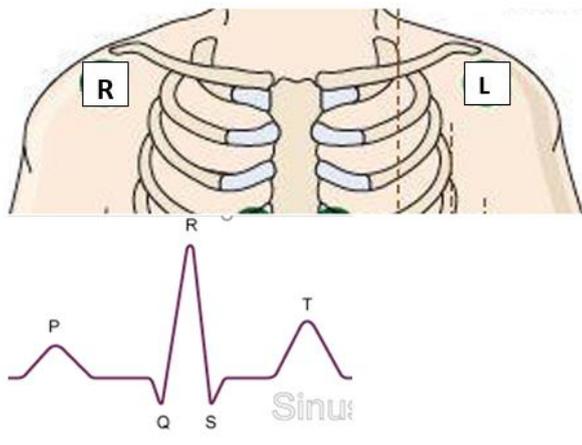
**Figure 12 EMG electrodes for extended montage**

#### **4.3.2 Cardiorespiratory parameters**

Cardiorespiratory channels included one electrocardiogram (ECG) channel and three respiratory recording channels. Respiratory channels consisted of airflow, chest and abdomen.

## Electrocardiogram (ECG)

The ECG signal for assessing cardiac function was recorded using by modified lead I channel. One electrode was placed on the right shoulder over the anterior deltoid and a second electrode placed on the left shoulder anterior deltoid (Figure 13).



**Figure 13 ECG electrode position for modified ECG lead 1**

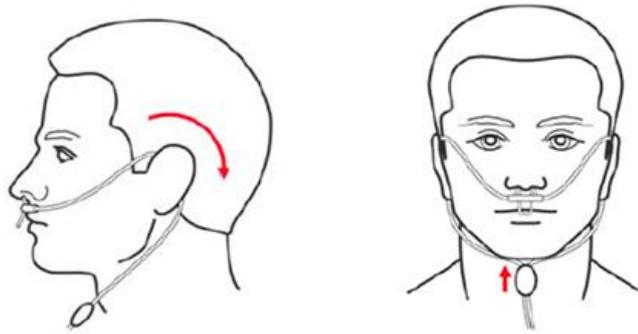
The amplifier settings were 0.5 Hz to 70 Hz for filters and a sampling rate of 254. Amplification requirements for the recording of the ECG signal varied according to each patient, but was adjusted to allow visual identification of P-wave, QRS complex and the T-wave. Unimed EEG cup electrodes were applied with Hypafix adhesive tape, Ten20 electrode paste and collodion was applied around the edges of the electrodes.

## Respiratory

Respiratory monitoring during sleep included techniques for assessment of oral-nasal airflow and thoracoabdominal movements to measure respiratory effort.

## Oro-nasal airflow

An oronasal thermistor was placed so that the nasal prongs rested just at the entry of nostrils and the oral prong rested over the philtrum, extending just past the cupid bow of the upper lip (Figure 14).



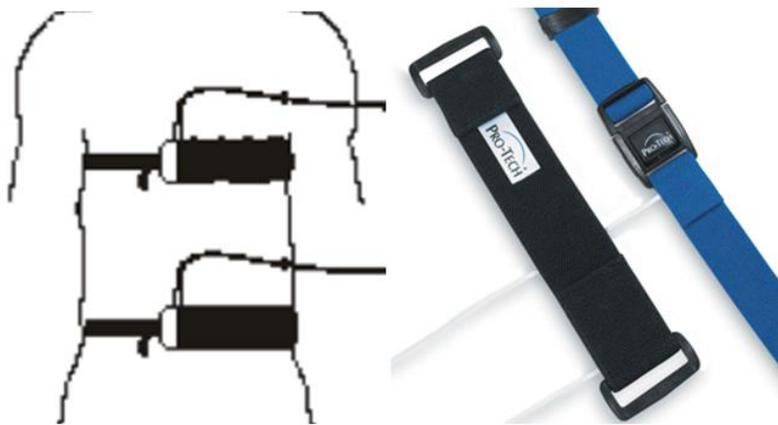
**Figure 14 Oro-nasal thermistor set up for recording the airflow**

Prior to placing these sensors, and if necessary, the position of the nasal beads of the thermistor was adjusted by bending them forward to prevent them from riding up into the nostrils while keeping them exposed to exhaled air. The connection lead was secured in place by looping the wires over and around ears and gently securing the slides by the neck. Additional tape was placed to further secure the leads at the cheeks, just laterally to nasolabial fold. Sensitivity was set to allow peak-to-peak deflection of 10 mm. Filters were set at 0.1 to 15 Hz and the sampling rate was set at 100.

### **Respiratory effort**

A piezoelectric sensor is typically used for monitoring subjects' respiration. The sensor was combined with an elastic belt to construct a belt-sensor gadget where the output signal is proportional to the expansion of the belts. For this study, the respiratory effort equipment units supplied by Pro-Tech (Figure 15) were used for both the chest and abdomen to obtain respiratory effort measurements. To maximise the quality of recorded signals, the chest band was placed under the left armpit, with the lead wire facing upwards near the nipple line (or mid-chest); the abdominal band was placed on the left side of the body at the level just above the umbilicus with the lead wire facing upwards. If a respiration effort belt is placed around the hips, there will be little to no change in the cross-sectional areas during diaphragmatic excursions.

Another consideration is belt placement. Both chest and abdomen belts were placed on top of the regular indoors clothing, as this was considered less intrusive. They were made secure, but not too tight. The rationale for this is that if the belts were placed too tight, causing the actual cross-sectional change of the chest or abdomen to be restricted, they would not reflect the patient's true breathing effort. Conversely, if the belts were placed too loosely, the belts would tend to move and may overlap one another. The sensitivity was set to give a deflection of amplitude of 10 mm peak to peak while breathing normally. Filters were set at between 0.1 and 15 Hz. The sampling rate was set at 100 samples per second.



**Figure 15 Respiratory effort electrode assembly**

Once all the sensors were put in place, leads for neurophysiological and cardiorespiratory parameters were bundled together and routed behind the back of the neck forming a pony-tail leading to the head box amplifier. The electrodes and the head box were secured with net-last bandage and placed into a specially designed jacket that was worn by the patient (Figure 16). A long cable of about 10 m linked the patient to the recording system. When necessary, the linking cable could be disconnected temporarily when the patient needed to move further than 10 m from the recording system. The whole set up allowed flexibility of movement within the house area.



**Figure 16 Fully set up patient for HVTP recording**

#### **4.3.3 Audio-visual data**

The audio-visual recording consisted of a video camera that was mounted on a tripod directly in front of the bed about one metre from the foot end of the bed. The tripod was fixed to the side end of the recording trolley (Figure 8). X-vision and DSP260 digital video cameras were used. The setting was adjusted so that a wide-angle view of the bed and the surrounding area was within the visible range of the camera. The trolley was positioned such that it was possible to manually rotate the camera without interfering with the setting. The patient was instructed to check the position and quality of the picture just before settling to sleep and make any adjustment as necessary and, if needed, to contact the researcher by the phone. The recorded audio-visual data was stored in the recording area of the computer's hard drive simultaneously with the rest of the electrophysiological data.

#### **4.4. Procedure for data acquisition**

##### **4.4.1 Biological calibration**

Biological calibration was conducted to obtain baseline values and ascertain the quality of the recorded signal. This provided a reference while monitoring and for scoring and interpreting the PSG study. The patient was asked to lie in the position they would normally sleep or supine, if possible, throughout the calibration procedure. The quality of the signal was verified, or adjustments made as necessary, to the electrodes and sensors, or to the sensitivity, gain, polarity or filter settings. Annotations of instructions given during the calibration procedures were documented.

The following basic calibration procedure was carried out:

- i. With the patient lying quietly, they were asked to close their eyes for 30 seconds and then open them for another 30 seconds;
- ii. Lying quietly, either in a supine or in their usual sleeping position with eyes open, the patient was asked to look straight ahead for 30 seconds;
- iii. Lying quietly with eyes open, the patient was asked to look left, centre, and then right, without moving the head. This was done twice;
- iv. Lying quietly with eyes open, the patient was asked to look up, centre and down. This was done twice. The ceiling was used as the centre position when supine, otherwise the patient was asked to look straight;
- v. Lying quietly, the patient was asked to blink five times;
- vi. Lying quietly, the patient was asked to clench their jaw then grit their teeth;
- vii. Lying quietly, the patient was asked to flex their right foot, then their left foot. The process was done twice;
- viii. The patient was asked to breathe IN and OUT normally, and then take deep breaths IN and OUT. The patient was then asked to take a deep breath and hold for 10 seconds and resume normal breathing;
- ix. With arms in a supine position, the patient was asked to move their fingers repeatedly in a piano-playing simulation;
- x. A visual check of the picture on the split screen was carried out to ensure the whole body was visible including part of the surrounding area.

#### **4.4.2 The overnight recording**

In order to maintain the habitual sleep patterns of the patient, no stipulation was made as to when the patient should go to sleep, or what they should or should not do as far as their sleep related routine was concerned. They were only requested to make a note of the time when they decided to settle to sleep and when they finally woke up. The signals being recorded were left on display to act as feedback for the patient. They were at liberty to turn off the monitor if they wished.

The procedure for temporarily disconnecting to allow the patient to access essential areas that may be distant from recording equipment such as the bathroom was demonstrated. The patient was also given the opportunity to practice. Any questions or uncertainties were clarified. A telephone contact for the researcher was provided and the researcher was available for consultation throughout the period of the sleep study. An agreement was made as to the time that was suitable for the day two visit. A minimum of two nights recording was obtained. On the second day, the researcher went back to the patient's home to ensure the recording was optimal and to retrieve the data from the first night recording. Using the store and retrieve process, night one recorded data was transferred to an encrypted portable device in order to be transported to the hospital for analysis. Electrodes and other recording sensors were checked and optimised for night two recording. This was performed by visually checking the outputs on the screen.

The data acquisition was carried out using Viasys/Nicolet software of the home recording system which was also the software used to assist in analysis.

#### **4.5. Procedure for data quality analysis**

High quality biological signals are essential for the successful execution of clinical diagnosis. Several noise sources, internal or external, may contaminate the recording of biological signals. These sources can distort the signal and lead to errors in the interpretation of the study. In addition, in an untested environment, it is unclear whether

the recording equipment can withstand long periods of recording of multiple types of signals unmonitored.

Video EEG-PSG quality assessment can be considered to consist of three dimensions:

- i. Sufficiency which address the quantity of data acquired in terms of duration and continuity
- ii. Readability which address the quality of data recorded
- iii. Relevance which addresses the effectiveness of the recorded data in helping to answer the clinical question.

The present study deals mainly with the first two dimensions. In the present study, the quality assessment for each night of video EEG-PSG recording was performed in two levels and scored numerically.

- i. In the first level, the recording was checked for duration and continuity. The entire recording was checked for the duration of the total recording time and whether, during that period of the recording, the signals were recorded continuously without unexplained disconnections.
- ii. At the second level, analysis of signal quality of neurophysiological, cardiorespiratory and audio-visual channels was performed. The quality assessment for the physiological signal was based on that used by Redline et al. (1998) for sleep disordered breathing and subsequently applied by Campbell and Neill (2011), Iber et al. (2004), (Kapur et al., 2000; Portier et al., 2000) In the criterion used in these four studies, it was possible to assign quality assessments to specific recording parameters. However, as the four above mentioned studies only investigated sleep disordered breathing, it was necessary to modify this criterion in terms of physiological signal grouping to

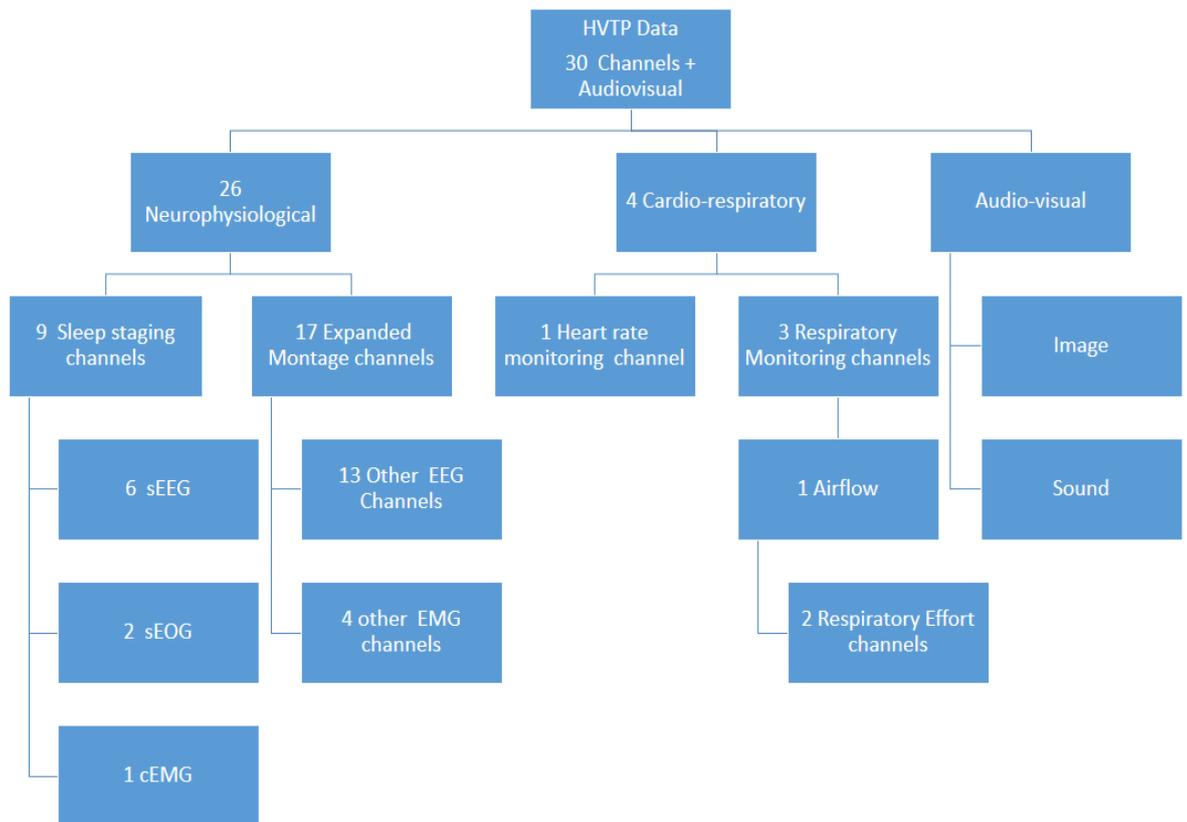
tailor them to the current study of parasomnias. For instance, in the above studies, 12 to 13 channels were used, compared to 30 channels in the present study. Each channel group was assigned a numerical score according to the duration, continuity and quality of the signal collected as described later.

In addition, since none of the previous studies included audio-visual recording, a separate criterion of video quality assessment was adopted for the present study. The criteria for visual and audio quality assessment was adapted from the International Telecommunication Union's recommendations (ITU) (ITU, 2014), as these recommendations provide clear and specific elements that can be graded.

#### **4.5.1 Procedure for assessing the quality of physiological measurements**

For each night, recording time was categorised according to the length of the recording, in a manner similar to that of previous studies (Redline et al., 1998b); (Kapur et al., 2000), except in the present study, the studies that fell under less than four hours and less than two hours were grouped together, as the significance for the two was the same in the present study since any recording of less than four hours was considered a failure (A. J. Campbell & A. M. Neill, 2011) . Thus, in the present study, the total recording time was assigned to one of three categories: more than six hours of recording time, between four hours and six hours, and less than four hours.

For practical reasons, channels were grouped into functional sets per their specific role in sleep studies. The first set consisted of neurophysiological data including EEG, EOG and EMG signals. This was further subdivided into sleep staging channels, movement quantification channels and seizure activity detection channels. The second set consisted of cardiorespiratory channels. The cardio-respiratory channels were further subdivided into respiratory monitoring channels and heart rate monitoring channels. The third set consisted of audio-visual signals, which were subdivided into image and sound. Figure 17 illustrates the functional channel grouping.



**Figure 17 Functional channel grouping showing the number and the function of signals recorded**

Each recording was then manually checked for interruptions. Only studies with a minimum of four hours of scorable data, with no interruptions on at least one respiratory channel (airflow or chest or abdomen band), one channel ECG, and sleep staging channels (EEG, EOG & cEMG) (Iber et al., 2004) were included in this analysis. For the expanded montage channels, at least three quarters of expanded bilateral montage channels for EEG, and at least one upper arm and lower limb EMG channels, were required. Those that did not meet the four-hour criteria were noted as failed and not analysed further.

A numerical grading system for duration, continuity and signal quality was developed for easy scoring in this study as described in the following sections.

#### **4.5.2 Procedure for assessing sufficiency in terms of duration and continuity of overnight recordings**

The total recording time was defined as being from the time the patient settles to sleep (lights out) to waking up (lights on). Continuous recording was defined as a recording that was unbroken throughout the recording period, or those with explainable interruptions associated with normal activity such as going to the bathroom. Minor interruptions such as those associated with amplifier saturations, or unexplained disconnections for periods of less than half of a 30 seconds' epoch, were noted. Studies with a total recording time of less than four hours, or those with a total recording time or more than four hours but with frequent interruptions, making sleep analysis impossible for at least four hour, were excluded from further analysis and documented as failed. The numerical score had a maximum of four points and a minimum of zero points. The scoring criteria for duration and continuity are summarised below in Table 9.

**Table 9 Duration and continuity criteria of HVTP data variables**

More than 6 hours	2
Between 4 and 6 hours	1
Less than 4 hours	0
No interruptions or explainable interruption such as going to toilet	2
Minor interruptions such as amplifier disconnection for less than 15 seconds	1
Longer interruption prohibiting sleep scoring or event quantification	0
Total score (Maximum=4, Minimum=0)	

#### **4.5.3 Readability quality assessment for neurophysiological signals**

The quality elements for neurophysiological signals for sleep scoring and other neurophysiological signals was adopted from the criteria applied by Duun-Henriksen et al. (2015). Although this scoring process is subjective in nature it was straightforward to apply, as the quality elements were clear and applicable, not only to the EEG signals, but also to the other neurophysiological signals. In the present study, numerical values were applied to the quality elements to make the scoring more objective. The quality of

assessed signals generally reflected the degree of obscuring associated with mains interference, other artefacts, and the degree of difficulty in analysis, which are all typical problems encountered in neurophysiological day-to-day recordings requiring re-montaging and adjustment of the standard settings. The quality for the neurophysiological functional group was assigned a numerical value as shown in Table 10.

**Table 10 Quality assessment for neurophysiological functional group as developed for this study.**

<b>i. Main interference filter</b>	
Filter not required	3
Filter helpful	2
Filter necessary	1
Filter not helpful	0
<b>ii. Other artefacts</b>	
No artefacts	3
Some artefacts not requiring filtering	2
Filtering necessary	1
Filtering does not solve the problem	0
<b>iii. Re-montaging</b>	
No re-montaging required	3
Re-montaging helpful but not necessary	2
Re-montaging necessary	1
Re-montaging does not solve the problem	0

Total score (Maximum= 9 and Minimum=0)	
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#### 4.5.4 Quality assessment for cardiorespiratory signals

Cardiorespiratory parameters including respiratory and ECG lead 1 signals were recorded throughout the study period. The quality appraisal of the recorded signals was manually carried out. The respiratory signal quality criterion was adopted from that developed by Redline et al. (1998). This scoring criteria was used as it reflects the current practice; further, as other studies have used similar criteria, it would allow the present data quality to be compared with others who have used a similar scoring system. However, as in other studies that have used a similar scoring system (Kapur et al., 2000; Portier et al., 2000), it was necessary to make some modifications for the present study. The percentage of total recording time with a satisfactory signal was visually assessed for each PSG channel. Significant disturbance was defined as the signal where relevant feature identification is erroneous, resulting in a false interpretation of the recorded physiological signal.

Thoracic and abdominal movements (piezoelectric strain gauges) for respiratory effort belts, or airflow in combination with any of the two respiratory effort channels, were required as a minimal prerequisite for quality analysis. Important features that were necessary for analysis were shape, amplitude, rhythmicity and synchrony of signals. The ability to identify amplitude, rhythmicity and synchrony depends on the quality of recorded signals. Numerical points were allocated per the percentage of the signal with good quality over the whole recording period (Table 11).

**Table 11 Respiratory signal quality assessments based on scorability**

Quality variable	Visual score
More than 90% scorable	3
80-90% scorable	2
50-80% scorable	1

50% scorable or less	0
Score (maximum =3 minimum=0)	

The ECG signal quality was based on the ability to visually identify the three main components of the ECG signal, a P wave, a QRS complex and a T wave, and scored according to the duration of the recording where the components are identifiable (Table 12).

**Table 12 Cardiac signal quality assessment based on quantity and ability to identify pertinent ECG components**

Quality variable	Visual score
Components identified in more than 90% of the time	3
Components identifiable in 80-90% of the time	2
Components identifiable in 50-80% of the time	1
Components identifiable in 50% of the time or less	0
Score (Maximum=3, Minimum=0)	

For both respiratory and cardiac signals, there was a maximum of three points and a minimum of zero.

In the cardiorespiratory group of signals, there was an extra category where these parameters were not recorded for various reasons as explained in results section. Although these would have been classified as failed procedures, other mitigating factors required an explanation. For example, one patient who was at the time suffering from severe cold making it difficult to record airflow, it would be difficult to associate this directly to quality. In another patient, the respiratory bands were of inappropriate sizes and could not be used.

#### **4.5.5 Quality assessment for readability of audio-visual signals**

The third set of the functional data consisted of audio-visual signals including sound and image. The audio-visual quality assessment was carried out each night.

Three samples were taken each night at different times during the sleep recording period. Each sample was ten minutes long. A first sample was taken just before the beginning of the sleep period as the patient settles to sleep. The second sample was taken halfway through the sleep period and the third sample just before and a few minutes after waking up.

In this study, evaluation was carried out subjectively using a typical 17-inch desktop computer screen to reflect the usual clinical setting. The minimum viewing distance was in accordance with the viewing distance guidelines for monitor placements for computer workstations (Ankrum, 1996). The ITU's guidelines (2014) were used in this project for the video and audio-visual quality assessments. The audio and video characteristics were analysed separately.

#### **Video quality**

Video quality can be evaluated objectively using mathematical models, or subjectively by asking users for their rating. Subjective rating was adopted in this project for two reasons; first, as the human eye is eventually the final recipient of the video picture, human visual perception was considered an important aspect of quality; and second, subjective quality analysis reflects the typical clinical setting. The quality judgement was made based on the picture quality and the content. Typically, the researcher watched three short sequences of the video each lasting ten seconds, and then rated them using the criterion outlined below in Tables 13 and 14. The sequences were pruned from the night recording and represented the beginning of the recording, the middle and the end. The video quality scoring of the image considered distortions related to camera quality or equipment positioning, poor setting selection, interference by the client, or client related activities, e.g., bedclothes etc. The researcher's subjective opinion of the video quality was also

formed through the influence of many different factors including colour, brightness, background stability, outline definition, etc.

Quality dimensions were assumed to define factors that contribute to the perceived global image quality, together with an indication of whether a factor contributes positively or negatively to quality. The content element added the feature of relevance but this was not used in quality calculation for this study. The scoring system developed for the present study provided a maximum score of fifteen points and a minimum score of zero.

**Table 13 Picture quality elements adapted from the International Telecommunication Union (ITU, 2014) for assessing video quality**

1=presence of positive or absence of negative quality 0=presence of negative or absence of positive quality
Brightness and contrast (positive)
Colour reproduction (positive)
Outline definition (positive)
Background stability (positive)
Speed in image reassembling (positive)
Jerkiness (negative)
"Smearing" effects (negative)
"Mosquito" effects/fuzziness (negative)
Double images/shadows (negative)
Halo (negative) personal bias
Total (0-10)

**Table 14 Picture content quality scoring developed for this study reflecting technical adaptability of recording system to home environment**

Variable	Score
Unobstructed-full body view/predetermined focused view well lit	5
Unobstructed-full body view/predetermined focused view/but stretched/end frame black	4
Unobstructed-full body view/predetermined focused view/but stretched/end frame black not well lit	3
Partial obstruction= but clear/focused well lit	2
Partial obstruction dark	1
No video	0

### **Audio quality**

The ITU's (2014) Absolute Category Rating method was used to assess audio quality. In this single stimulus method, the researcher listened to three clips each lasting ten seconds from the same night. Each clip was rated independently on a category judgement quality scale. The method specified that after each presentation the researcher subjectively evaluated the quality of the sequence. The audio data was then scored on a five-level scale for rating overall quality for audio quality, as outlined by the ITU's recommendations. The score for each night was the average score from the three clips reviewed (Table 15).

**Table 15 Audio quality based on the International Telecommunication Union (ITU, 2014) listening scale.**

Quality criteria	Score (ITU)
Complete relaxed listening: no effort required	5
Attention necessary: no appreciable effort required	4
Little required	3
Considerable effort required	2
No meaning understood with any feasible effort	1
No sound including background noise on playback	0

#### **4.5.6 Summary of data quality scoring procedure**

Quality assessments was carried out to inform sufficiency of data reordered and its readability using visual analysis. Sufficiency assessment was carried out on a four-point scale. Due to complexity associated with readability variables, signal quality of each group was scored numerically for each group of signals recorded.

### **4.6 Results**

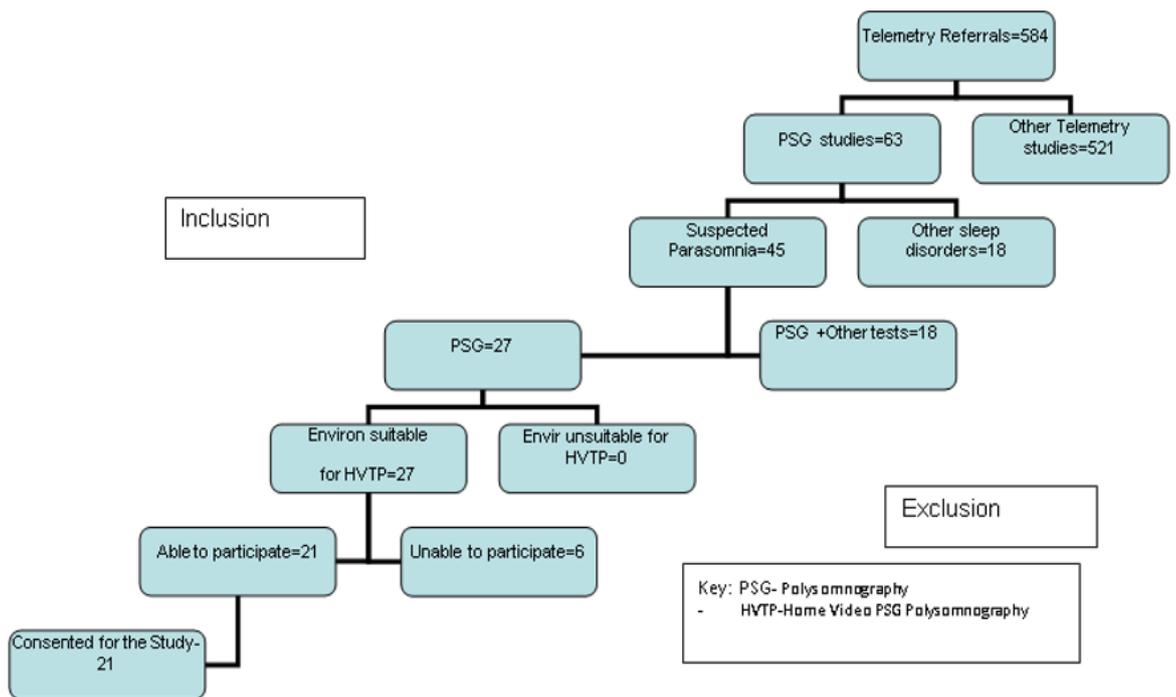
#### **4.6.1 Patient characteristics for the present feasibility study**

Between October 2014 and December 2015, 584 patients were referred to the Video Telemetry unit at King’s for diagnostic evaluation of various neurological problems including epilepsy, movement and sleep disorders (Table 16). Patients for the HVTP study were recruited from this group of patients (Figure 18).

**Table 16 Referral pattern to the video telemetry unit at King's College Hospital**

Period	Referrals
Oct/Dec 14	136
Jan/March 15	118
April/June 15	109
Jul/Sep 15	111
Oct/Dec 15	110
	<b>584</b>

Of the 584 patients referred to the telemetry unit, 63 patients were required to undergo assessment for suspected sleep disorders and required PSG studies. Of the 63 patients requiring PSG studies, 45 patients required to undergo assessment for parasomnias as the clinical question. Of the 45 patients with parasomnia as the clinical question, 18 required other tests that needed to be performed alongside the PSG studies. There were, therefore, 27 patients eligible for the present home studies. These 27 patients were all adults who lived within a 40-mile radius with a suspected diagnosis of parasomnia requiring sleep studies and, thus, fulfilled the eligibility criteria for the study. Figure 18 shows the selection process.



**Figure 18 Patient selection process**

Out of the 27 patients, 21 (78%) consented to participate in the study, two declined the study for personal reasons and did not wish to have the procedure in the hospital either, two preferred the test to be done in the hospital and were put on the waiting list for the hospital based sleep study, one was too ill to participate due to comorbidity and the procedure was at the time not considered appropriate at home or in the hospital, and one no longer required the test as their clinical situation had changed for the better (Table 17).

**Table 17 Study sample for those who were considered suitable for the study**

Completed the HVTP study	21
Preferred the study in hospital	2
Declined the study for personal reasons	2
Declined the study due to other medical issues	1
Test no longer required	1
Total eligible for HVTP study	27

All the 21 who consented went on to complete the study. Of the 21 who completed the study, 10 were men and 11 were women. Their ages ranged between 26 and 78 years with an average age of 52 years. In terms of clinical profiles, the most common suspected clinical problem, according to the clinicians' referral, was REM behaviour disorder (RBD) and periodic limb movements in sleep (PLMS), which accounted for 28.6% each. The differential of epilepsy verses parasomnia was also a common clinical question accounting for 19.0% (Table 18).

**Table 18 Suspected clinical profiles of the patients completing the study**

Clinical Problem	Number	%
REM behaviour disorder (RBD)	6	28.6
Periodic limb movements in sleep (PLMS)	6	28.6
Epilepsy vs parasomnia	4	19.0
Non-specific nocturnal disturbance	2	9.5
Nocturnal jerks	2	9.5
Somnambulism	1	4.8
Total	21	100

**4.6.2. Data sufficiency according to duration and continuity for each night recording**

The total recording time ranged from 217 to 760 minutes per night. A total recording time of less than 240 minutes was considered a failed study and excluded from further analysis. Of the forty-two nights' recordings (2 x 21 patients), one night contained data of less than four hours due to insufficient computer disk space; this was occasioned by failure to clear disk space prior to commencing the study. Therefore, all the results are based on 41 nights of recording. One night contained data of 274 minutes; this was relatively short but falling within the 4-hour cut-off limit, which was the minimum accepted sleep recording duration for the present study. The reason for this short recording was due to the patient's sleeping habits. This patient was a student who spent a lot of time awake working on the computer and surfing the internet. The remaining forty nights had data of more than six hours with no significant interruptions to the recorded data. The average total sleep recording time for studies included in the analysis was 552.8 minutes per night. Overall, out of a maximum score of four points (as described in the

previous section), duration and continuity score was four points in 39/41 (95.2 %), 3 points in 1/41 (2.4%) and two points in 1/41 (2.4%) as shown in Table 19.

**Table 19 Duration and continuity quality score reflecting sufficiency of recorded data**

Point scored-0-4	Number of nights
4 points	39(95.1 %)
3 points	1(2.4 %)
2 points	1(2.4 %)
1 points	0
0	0
	41

#### **4.6.3 Sleep scoring neurophysiological channels**

On the sleep scoring channels including sEEG, EOG, and cEMG channels, 41 nights were analysed. For the signals with a possible maximum of score of nine points, a score of six point or more indicated that the signal was easily readable or required very little adjusting by the reader. Out of a maximum of nine points, 39 (95.1%) scored six points or more points, 1 (2.4%) scored five points, 1 (2.4 %) scored 2 points and none scored 0 or 1 point. By combining those signals scoring six or more points, the overall quality of sleep scoring channel recordings was therefore readable in 95.1 % of the recordings. Table 20 shows sleep scoring channels quality ratings.

**Table 20 Sleep scoring neurophysiological channels rating per the criteria outlined in the procedure section**

Readability Criteria	Point score (0-9 points)	Sleep staging
Readability as assessed by the degree of mains interference, other artefacts or need for re-montaging as described in the procedure section	8-9	32(78.0 %)
	6-7	7(17.1 %)
	4-5	1 (2.4 %)
	2-3	0
	0-1	1 (2.4 %)
Total nights		41

#### **4.6.4 Extended montage neurophysiological channels for event scoring**

The extended montage channels included other EEG channels that consisted of all other scalp channels excluding those used for sleep scoring and other EMG channels, which included all other EMG channels that were not used for sleep scoring. Quality in these was rated using same criteria as sleep scoring neurophysiological channels. The extended montage channels consisted of EEG channels which were not required for sleep scoring and all EMG channels that were not required for sleep scoring. These extra channels were required for movements scoring or seizure activity detection. As shown in Table 21, for both groups, of the 41 nights analysed, 39/41 (95.1%) scored six or more points, 1/41 (2.4%) scored 5 points and 1/41 (2.4%) scored two points. A score of 6 points or more indicated that the signal was easily readable or required little adjusting by the reader.

**Table 21 Extended montage channels rating for seizure activity detection and movement scoring.**

Readability Criteria	Point score (0-9 point)	Other EEG - extended montage	Other EMG- extended montage
Scoring readability as assessed on the degree of mains interference, other artefacts or need for re-montaging as described in the procedure section	8-9	35 (85.4 %)	32 (78.0%)
	6-7	4 (9.8 %)	7 (17.1 %)
	4-5	1(2.4 %)	1(2.4%)
	2-3	0	0
	0-1	1(2.4 %)	1(2.4%)
Total nights		41	41

#### **4.6.5. Cardiorespiratory channels**

Signal quality indicators for cardiorespiratory channels were considered as measured parameters that can estimate the reliability and accuracy of cardiac and breathing patterns. Of the 41 nights monitored, respiratory parameters were not recorded on two patients (four nights). One of the patients was suffering from a bad cough at the time of the study and found the respiratory parameter difficult to manage. Regarding the second patient, there were no appropriate sizes for the respiratory bands. In this group, a score of two points or more indicated that the signal was easily readable or required little adjustment. Out of 41, 35, representing 85.4% scored more than two points, 1/41(2.4%) scored one point, 1/41(2.4%) scored zero points and 4/41 (9.6%) scored no points as they were not recorded in these patients.

A typical ECG waveform of a single normal heartbeat consists of three characteristic waves: P wave, QRS complex and T wave. A high score of 2 or more points indicated that these waves were easily visually identified with little or no obscurity. Table 22 shows the scores obtained in these cardiorespiratory parameters. The ECG quality in this study was high with 40/41 (97.6 %) scoring 2 out of 3 points or more; 1/41 (2.4%) scored one point and none scored zero point, as shown in Table 22.

**Table 22 Cardiorespiratory quality rating using criteria described in the procedure section**

Score points (0-3 points)	Respiratory	Electrocardiogram
3	23 (56.1 %)	33 (80.5 %)
2	12 (29.3 %)	7 (17.1 %)
1	1(2.4 %)	1(2.4 %)
0	1 (2.4 %)	0
Not done	4(9.6 %)	0
	41	41

#### 4.6.6 Audio-visual

The video was assessed on the clarity picture and the content in the picture. A combined score of 9 points or more out of fifteen indicated that the picture and contents were identified by eye with little or no difficulty at all. Of the 41 nights of recording included in the analysis, 39/41 (95.1%) scored nine or more points out of fifteen and 2/41 (4.9%) scored five or less points out of fifteen as shown in Table 23.

**Table 23 Video quality rating**

Manual score of video: 0-15	Nights (%)
12-15	25(61 %)
9-11	14(34.1 %)
6-8	0
3-5	2(4.9%)
0-2	0
	41(100 %)

Audio signal was assessed on whether it was audible and clear. A score of four points or more indicated a signal that was easily audible and clear or required little listening effort. For audio signal, 33/41 (80.5%) scored five out of a maximum of five points, none scored four points, 4/41 (9.8%) scored two out of five points requiring considerable effort to comprehend. 4/41 scored zero to one points with one of these having no sound recording at all. These were incompressible and hence considered unusable (Table 24).

**Table 24 Audio quality rating**

points scored (0-5 points)	No of nights (%)
5	33(80.5%)
4	0
3	0
2	4(9.8 %)

1	3(7.3 %)
0	1(2.4 %)
	41

#### 4.6.8 Summary signal quality in terms of sufficiency and readability

The quality of recorded physiological and audio-visual signals determines the ease and confidence in which the reader can extract the relevant information from the signals to make a clinical judgment. A signal that does not require the reader to make any adjustments such as filtering or re-montaging or requires minimal adjustments can be considered to be of high quality. Sometimes the signals become readable after major adjustments and these can be considered acceptable whereas other signals are unreadable despite adjustments and hence considered as unusable. In this study, those that required no adjustments or minimal adjustments were grouped together since they were more or less the same in terms of readability. Table 25 shows the summary results of all the signal quality of various signal groups in terms of sufficiency and readability.

**Table 25 Summary showing quality in terms of sufficiency and readability of data recorded**

Signal quality based on points scored	Sufficiency Duration & Continuity	Readability						
		Sleep Chanls	Other EEG	Other EMG	Resp-iratory	ECG	Video	Audio
High score-sufficient and easily readable	40	39	39	39	35	40	39	33
Acceptable score-sufficient and readable with difficulties	0	1	1	1	1	0	0	0

Low score - insufficient & unreadable or unrecorded	1	1	1	1	1	1	2	8
unrecorded	0	0	0	0	4	0	0	
Total	41	41	41	41	41	41	41	41

## 4.7. Discussions

### 4.7.1 Summary of findings from the HVTP data

This strand of the study explored the feasibility of HVTP as a diagnostic method for assessing patients undergoing investigations for parasomnias by looking at the quality of data recorded. Twenty-one patients, 11 men and 10 women, aged between 26 and 78 years, underwent HVTP for two nights in their own homes. Suspected REM sleep behaviour disorder (RBD) and Periodic Limb Movements in sleep (PLMS), as well as the differential diagnosis of epilepsy verses parasomnia, were the common clinical problems accounting for 16 out 21 (76%) of the patients' studies.

The findings show that, overall, as per the criteria developed for this study, recordings obtained were sufficient in terms of duration and continuity to allow for sleep analysis in 97.6% of the nights recorded using the developed objective quality criteria. Signals for neurophysiological sleep scoring was easily readable in 95.1% of the studies. Cardiorespiratory signal was easily readable in 97.6% for ECG and 85.4% for respiratory signals. Signal for other EEG and other EMG channels for extended montage were easily readable in 95.1% for both channel groups. Video characteristics were easily recognisable in 95.1% of cases and audio signal features were easily recognisable in 80.5% of the cases.

### Feasibility

The objective diagnosis of specific sleep disorders is usually based on inferences drawn from the specific electrophysiological or behavioural sleep data features extracted from sleep recordings. According to Li, Mark, and Clifford (2008), the quality assessment for physiological signals plays an important role in the accurate characteristic estimation and

is crucial for clinical judgment. Due to the uncontrolled environment in the field of pervasive healthcare, the quality of physiological signals is variable. One of the main reasons for the decrease in signal quality is the lack of online intervention in unattended environments, in the case of signal degradation, compared to the case in an attended environment where the practitioner corrects signals as required. Another difficulty encountered in home sleep studies is the lack of correlation between the physiological signals and patients' behaviour. Unlike in the laboratory, where the clinical staff can document the behaviour of the patient to some extent, such information is not readily available in-home studies unless video recording is also carried out simultaneously.

Home sleep recordings have been carried out for many years to assess sleep disorders including periods earlier than 2007 which was used as cut off for the literature review for this study. However, there seems to be great variation in the way these studies are carried out and the outcomes reported. The main variations have been in the number and types of parameters monitored, the location and personnel carrying out the set up, and the methods of analysis. For instance, in Rosekind, Coates, and Thoresen's (1978) earlier work, sleep studies from patients' homes were recorded using an eight-channel portable device without video recording. The set up in that study was carried out by the technician in the patient's home and consisted only of sleep features. Only two patients' data was unusable, representing a failure of 6.25%. Redline et al. (1998), in a multicentre study with the set up and calibration at the patients' home, reported a failure of 5.3% with sleep staging submental EMG contributing most to the failure. Conversely, Portier et al. (2000), using a method where the set up was performed in the laboratory with the patient taking the portable device home and bringing it back to the testing centre the following morning, reported a failure rate of 20%. In the present study, the set was carried out at the patients' homes and the failure rate was 2.4% with 95.1 % of the records being easily readable requiring little or no signal manipulation and a further 2.4 % being readable after signal manipulation.

By taking advantage of developing technology, more and more sleep parameters can be recorded in the home environment. For instance, using only audio-visual and

cardiorespiratory parameters, Jacob et al. (1995) found that high quality and diagnostically informative recordings could be obtained for these signals in the home setting. In 2008, a compact telemetry-based monitor recording of neurophysiological, cardiorespiratory and audio-visual data was successfully trialled in patients with fibromyalgia (Ayappa, Norman, Seelall, & Rapoport, 2008).

Although many home sleep studies have been carried out in the last forty years, the variety of measures applied in different reported studies indicates that no general measurement of signal quality or study quality for PSG studies exists. Several factors might be considered to contribute to this deficiency of the current sleep study systems. Firstly, there is the general lack of clarity in defining what constitutes good quality data in sleep studies. Secondly, the existence of different types of sleep study recording systems with variable multiple channels makes it difficult to quantify what is sufficient to qualify as a standard in the light of heterogeneous clinical scenarios encountered in sleep medicine. Thirdly, with complex multiple channel recordings in many sleep studies, the issue of relevance of the different signals to clinical questions is not always clearly addressed. Fourth, there are obvious logistic and technical challenges associated with unattended recording in undedicated home environments. As physiological signal monitoring systems become common and more complex, evaluating the quality of the signals recorded in the home environment continue to be fundamentally important. Quality assessment of signals recorded in this present complex tri-modal HVTP was carried out for the different modalities including neurophysiological, cardio respiratory and audio-visual parameters. The results of the present feasibility study show that, in terms of data quality, HVTP can be recorded successfully at home in patients being assessed for parasomnia.

#### **4.7.2. Quality evaluation of recorded data**

Quality can be considered as the degree to which an object (entity) (e.g., process, product, or service) satisfies a specified set of attributes or requirements (Cooper, J, & Fisher, 2002). The quality of something can be determined by comparing a set of inherent characteristics with a set of requirements; depending on how well those requirements

are met, excellent or poor quality can be achieved (ISO, 2015). In home sleep recordings, the clinical assessment of the patient's condition ultimately relies upon the features extracted from the signals recorded in the home environment. The importance of a data feature is best defined in terms of its diagnostic quality (Jea et al., 2008). It is, therefore, critical that the issues of data quality are clearly addressed before the data obtained in such undedicated environments are utilised for clinical purposes.

Physiological signal detection approaches in unsupervised environments must examine either overall waveform quality, which could be associated with excessive artefact contamination, or inherent signal features that would indicate poor measurement techniques. A signal or group of signals could be disturbed if the characteristics of those signals result in difficult interpretation of the recorded physiological signals or are insufficient for the intended purposes.

In the present HVTP study, assessment of the signal quality was done at multiple stages of the system. In the first stage, the entire recording was assessed for duration and continuity of the recorded data to address the issue of sufficiency. In the second stage, various channels of the multi-parameter signals were grouped per their function. In the third stage, the morphological features of the physiological signals on each channel were evaluated to obtain signal quality estimates to identify the presence and level of noise or corruption in the signal. Each channel within the group was then weighed on its influence on the group by the estimate of the value of the signal on that group. Finally, the scores for each channel within the group were averaged to provide a quality score for the group to the grading system developed for this study. The results of this feasibility study show that HVTP can be recorded successfully at home in this group of patients with signals being easily readable in over 91% of cases, with the exception of audio, in which audio was easily comprehensible in 80% of the recordings. Table 25 summarises the results of quality assessment.

In one patient with unusual limb movements, despite having a high score in terms of video quality, bedclothes covered the area of interest and the interpreting clinician considered that it was difficult to make a definitive decision on the diagnosis without a

clear view of the area involved in the movements. As a result, a recommendation was made to repeat the test in the laboratory environment. In the present study, emphasis was laid on sufficiency in terms of duration and readability, in terms of data quality. However, the inability to make clinical decisions for the above-mentioned patient highlights the importance developing a quality criterion that addresses the relevance of the data being recorded in the light of the clinical question. For example, a patient being investigated for REM sleep behaviour disorder (RBD) may have a dream enacting behaviour episode in the first two hours of sleep and gets disconnected for the rest of the study period. According to the quality criteria developed for this study, it would have been considered failed although a diagnosis could clearly be made on the basis of the two hours recorded prior to the episode.

#### **4.7.3. The present 'gold standard' for sleep studies is not practical for all clinical scenarios**

Due to rapidly changing technology and the fact that sleep disorders are not one single entity according to the ICSD-3 (AASM, 2014), there is growing interest in sleep and sleep related disorders leading to a proliferation of various forms of sleep studies. The AASM distinguishes four levels of sleep studies depending on the number of channels with Type 1 being considered the gold standard (Ferber et al., 1994). This gold standard, while suited for respiratory related sleep disorder, is not suited for other disorders such as parasomnias. The European guidelines (Pevernagie et al., 2006) have recommended the inclusion of video recording, but the number of EEG and EMG channels are limited; this makes it inadequate for parasomnia where epilepsy might be a differential diagnosis. For the diagnosis of parasomnia or sleep-related seizure disorder, the sleep-scoring channels (EEG, EOG and cEMG) and an expanded bilateral montage, with full scalp EEG channels, extra EMGs for body movements (anterior tibialis or extensor Digitorum) are essential in addition to audio-visual recording and documented technologist observations during the period of study (Kushida et al., 2005).

The current reference standards can be improved by considering two important features. First, there is a need to recognise the importance of extra EEG and EMG channels that are

tailored to specific clinical scenarios. According to Burbric, Yazdani, and Pavlova (2014), combined PSG–EEG, utilizing 18-channel EEG, is an under-utilised technique that can assist in diagnosing paroxysmal nocturnal events and differentiate between the presence of a primary sleep disorder, seizure activity, or both. Indeed, for the diagnosis of complex parasomnias and nocturnal epilepsy, more EEG and EMG recordings are needed (Fischer et al., 2012). The Sleep Innsbruck Barcelona (SINBAR) group found that extra EMG channels were useful in detecting the motor and vocal manifestations occurring in RBD (Iranzo et al., 2011). The actual number and selection of channels used for a PSG recording depends on the disorder being investigated (Kushida et al., 2005). Each individual clinical problem is unique and it is necessary for diagnostic purposes to have a distinctive combination of signals and data features that fit the specific clinical situation.

Another important feature is taking advantage of advancing digital technology. Many PSG systems can easily have audio-visual recording incorporated into them allowing video to be recorded routinely. Video-PSG recordings are particularly important for the recognition and diagnosis of parasomnias and nocturnal epilepsy (Aldrich & Jahnke, 1991) (Derry, Harvey, Walker, Duncan, & Berkovic, 2009); (Tinuper et al., 2007). For some disorders such as sleep bruxisms, PSG including audio and video monitoring is considered a gold standard as a diagnostic tool (Carra, Huynh, & Lavigne, 2012); however, this can be complicated at the practical level since several nights of recordings should ideally be made in order to detect its fluctuations. Multiple night recording is often required to capture an event.

The advantage of having a setup of comprehensive HVTP, as proposed in this study, is that it can be adapted to the individual patient's clinical problem and that recordings can be extended to more than one-day recording as it is done in the patients' homes where there is less pressure on hospital beds. A PSG study that can record neurophysiological, cardiorespiratory and audio-visual signals, while adapting to the individual patient's needs in their own environment is 'the gold standard' and the present study has demonstrated that such a recording strategy is feasible.

#### **4.7.4. Technical considerations and challenges**

A few potential technical problems related to the collection of complex data in unattended and diverse settings were identified. First, HVTP monitors the patients during their daily activities; hence, it inherently raises the possibility of signal disturbances associated with such activity, especially regarding the movements of the person being monitored. Second, the procedure and on-going monitoring consists of complex multi-signals requiring technical expertise, hence, limiting what the patient could do by themselves in the unattended period. Third, there is the challenge associated with the variable lay out of home environments such as space to attach the leads and lay the equipment, and interruptions from other domestic related interests including phone calls, other family members etc., during the process of attaching the leads. Fourth, some home environments are electrically hostile due to other electrical equipment in the room. A common problem encountered in this study was the mains interference artefacts that were encountered, particularly in EEG and EMG channels, thus, reducing the ability to analyse the data unless a 50Hz filter was applied. Fifth, being attached to so many sensors on different parts of the body tended to cause discomfort, especially the oronasal-oral airflow sensors. A survey by Pantelopoulas and Bourbakis (2010) compared different approaches and emphasised multimodal physiological sensor systems for the early detection of symptoms; they concluded that that the trade-off between the comfort of the measurement device and the signal quality is an important challenge to be solved. However, it is worthwhile noting that the problem of discomfort is not unique to home based studies as the same type of sensors would equally apply even if the procedure was carried out in the laboratory setting.

#### **4.7.5. Limitations**

The present study had several limitations. Firstly, the equipment used was modified from the equipment system normally used for VET for the assessment of patients suspected of seizure disorder. It was difficult in the present study to incorporate a synchronised oximeter into the recording system, hence, oximetry was not evaluated. This can be

viewed as a major limitation as oximetry is considered one of the main parameters in sleep studies, although its role in parasomnias may not be significant.

Secondly, the researcher performed the data quality analysis, although the reporting clinician reviewed the data for clinical purposes. In assessing data quality, knowledge, experience and personal judgements all contribute to how one scores an item. In a study such as the present one, collaborating information and addressing inter-rater variability lends more credence to the results of the study. Thirdly, the study evaluated 21 patients drawn from one institution. Although the results of this study may be relevant to the local institutional requirements, a larger number of subjects drawn from a multicentre study would provide results that are more generalisable.

#### **4.7.6. Implications**

The results of the present study have several important implications. Firstly, home sleep studies have largely been limited to patients suspected of respiratory related sleep disorders. A major difficulty in using home sleep studies for non-respiratory sleep disorders is the failure rate associated with the need to record more physiological signals and the need to correlate these physiological signals with patient behaviour. The present study has demonstrated that it is not only possible to record many physiological parameters, but also that the recorded data is of a very good quality. A larger scale study is therefore feasible and warranted.

Secondly, many non-respiratory sleep disorders such as parasomnias are characterised by behaviour events that are sporadic, unpredictable and often environment sensitive. The ability to monitor these patients at home means the procedure can be tailored to the patient, not only by varying the duration of recording accordingly, but also by allowing the patient to sleep in their natural environment, thus, increasing the chances of capturing a habitual parasomnia event.

Thirdly, the pressure on the availability of hospital beds for elective procedures and the rising cost of performing laboratory sleep studies means that the need for more efficient ways of addressing sleep disorders cannot be ignored. Home sleep studies are one way in which this pressure can potentially be alleviated. The positive results of the present feasibility study provide a strong base for designing a larger scale study to evaluate the effectiveness of this form of sleep study and potentially making it a standard procedure.

## **Chapter 5: Patient acceptability of Home Video Telemetry Polysomnography (HVTP)**

Home video telemetry polysomnography introduces several unique aspects that warrant consideration to inform its acceptability as a viable clinical service in the assessment of sleep disorders. Firstly, the process involves taking what is typically done in a hospital setting to the patient's environment with the potential to create territoriality issues. Territoriality is the term used to describe the state that is characterised by possessiveness, control and authority over an area of physical space that provides security, privacy, autonomy and self-identity, all of which are important for well-being (Hayter, 1981). Patients feel anxious when an invasion of their territorial space occurs (Allekian, 1974).

Social and familiar environments have great impacts on sleep, especially regarding daily routines (Hart, 2010). A study of territoriality in Japanese adolescents indicated that the bedroom plays an important role in the establishment of territoriality in everyday life (Omata, 1995). The very nature of studying sleep and sleep disorders necessitates encroachments of these private spaces by the investigator.

Secondly, the inclusion of audio-visual recording simultaneously with other biophysiological parameters is generally not part of the standard Type 2 PSG home recordings. Inclusion of continuous audio-visual recording may potentially present concerns of importance to the patients being investigated. For instance, video recording could be considered an invasion of a person's privacy and constitute a threat to their dignity and personhood. It may violate a person's right to privacy, especially in case of misuse (Petrini, 2011). In addition, a camera intended to monitor one resident who has consented to its use may also inadvertently capture another resident who has not consented.

Thirdly, compared to Type 2, home recording system HVTP has more neurophysiological sensors to allow adequate investigation of parasomnias where nocturnal frontal lobe epilepsy may be a differential diagnosis; this implies applying more sensors to the patient. These added aspects, which have been integrated in the proposed HVTP recording

system, entail what might potentially be construed as personal space and territorial encroachment.

Few studies have reported on the acceptability of standard Type 2 home sleep studies. Bruyneel and colleagues (2013) reported that 20/21 patients in their study preferred to have the test at home (Marie Bruyneel et al., 2013); but there are no studies that have explored the patients' perspectives on Home PSG studies with extended montage synchronised video recording. Even the few studies that address this issue reported differences in patients' preferences with some reporting that, overall, patients preferred the hospital setting (Fry, DiPhillipo, Curran, Goldberg, & Baran, 1998); (Portier et al., 2000) and others reported that patients preferred the home environment (Campbell & Neill, 2011). There are, therefore, grounds to explore whether patients undergoing the HVTP process would find it acceptable.

The purpose of this qualitative phase of a mixed research method, therefore, was to explore the views and experiences of patients undergoing HVTP for assessment of parasomnia, to inform the acceptability of this form of clinical assessment. Acceptability refers to determining how well an intervention will be received by the target population and the extent to which the new intervention or its components might meet the needs of the target population and organisational setting (Ayala & Elder, 2011).

Qualitative research is a form of scientific inquiry that spans different disciplines, fields and subject matter and comprises many varied approaches (Denzin & Lincoln, 2000); it is particularly suited to exploring in depth the reasons why an intervention might be acceptable or not (Hopton, Thomas, & MacPherson, 2013). The aim of qualitative research is to develop concepts that can help us understand social phenomena in natural settings, giving emphasis to the meanings, experiences and views of the participants (Mays & Pope, 1995); it also helps to identify the cultural and social factors that hinder or encourage service use (Peremans, Hermann, Avonts, Van Royen, & Denekens, 2000). It is, therefore, appropriate for this study.

## **5.1 Methods**

### **5.1.1 Participants**

The sample for the qualitative study was derived from the main study, whose aim was to explore the feasibility of HVTP in terms of physiological and audio-visual signal quality, cost implications and patients' acceptance. The participants were selected from patients referred to King's College Hospital for evaluation of parasomnia or other conditions, where a question of events occurring at night required clarity, as is the case with nocturnal frontal lobe epilepsy. All those patients who were enrolled to take part in the HVTP feasibility study were approached to participate in the qualitative aspect of the study.

A total of 24 interviews were conducted with 12 patients; two per patient. These were conducted sequentially as the project progressed. The sixth patient interview was abandoned due to language difficulties. Although all 21 patients in this study had consented to the interview, data saturation was achieved with the 24 interviews. Of the interviews that were conducted successfully, seven participants were males and five females. The ages ranged between 34 and 78 years, with an average age of 54.25 years. Clinical profiles of the patients consisted of four suspected of REM behaviour disorder (RBD), four suspected of periodic limb movements in sleep (PLMS) and four with complains of nonspecific nocturnal disturbances causing awakening from sleep. Eleven patients interviewed were either married or in cohabitating relationships, and one lived with their parents. Seven patients were interviewed with their bed partners or a relative present.

### **5.1.2 Data collection procedure**

One advantage of qualitative methods in exploratory health research is that the use of open ended questions and probing gives participants the opportunity to respond in their

own words, rather than forcing them to choose from fixed responses (Mack, Woodsong, MacQueen, Guest, & Namey, 2005). There are three fundamental types of research interviews: structured, semistructured and unstructured (Gill, Stewart, Treasure, & Chadwick, 2008). Semi-structured interviews consist of several key questions that help to define the areas to be explored, but that also allow the interviewer or interviewee to diverge in order to pursue an idea or response in more detail (Britten, 1999). The semi-structured interview format is used most frequently in healthcare, as it provides participants with some guidance on what to talk about, which many find helpful (Gill et al., 2008). Semi structured interviews allow questions to be prepared ahead of time, allowing the interviewer to be prepared, yet they give the participant freedom to express views with his/her own words (Stuckey, 2013).

A face-to-face semi-structured open-ended interview was, therefore, adopted for this study; this would provide an understanding of the experience of patients who were undergoing HVTP, and how they viewed their experience of the process regarding the acceptability of the procedure. The interview was conducted in two parts. Both parts one and two were allocated 30 minutes each. Part one of the interview was conducted on the first day of the HVTP study. Part two of the interview was conducted on the third day, which was the last day of the HVTP procedure. The interview schedule across the two parts consisted of eight questions, four for part one and the other four for part two. The interview schedule is outlined in Appendix 7.

The interviews were based on the style suggested by Spradley (1979), in terms of developing rapport and attaining meaningful information. This style of qualitative interview has the advantage of being able to model the interview as a friendly conversation in an informal manner, while also being able to integrate descriptive, structural and contrast questions. The first part of the interview, on day one, generally explored what it meant for the patient to have sleep problems, and to know their perception and views on the diagnostic procedures. This first part of the interview was intended to develop rapport with those being interviewed and to gauge the scale and nature of the problem by exploring the patients' perspectives, attitudes and concerns

about the HVTP. The second part of the interview was conducted at the end of the HVTP procedure. This part of the interview was intended to explore the patients' experience of undergoing the process of HVTP.

According to Hertzog (2008), the choice of interview location (who chooses and what place is chosen) is not just a technical matter of convenience and comfort, but rather it is examined within the social context of the study being conducted and analysed as an integral part of the interpretation of the findings. However, for practical reasons, in the present study the interviews were conducted in the patients' homes by the researcher with their informed consent.

The interviews were audio recorded. The use of a digital recorder is undoubtedly the most common method of recording interview data because it has the obvious advantage of preserving the entire verbal part of the interview for later analysis. Tape recording has been described as one of the two most usual methods for preserving information collected in interviews (Gall, Borg, & Gall, 1996). It has been recommended that all interviews should be tape recorded and transcribed verbatim afterwards, as this protects against bias and provides a permanent record of what was and was not said (Pontin, 2000). Furthermore, the recording of the interview makes it easier for the researcher to focus on the interview content and the verbal prompts and, thus, enables the transcriptionist to generate a "verbatim transcript" of the interview (Jamshed, 2014). This process of audio recording, transcribing and analysing textual data is still the accepted norm (Markle, West, & Rich, 2011). A verbatim record of the interview is clearly beneficial in facilitating data analysis by bringing researchers closer to their data.

Although the participants were aware of the interview process, it was felt that conducting the interview on the same day as the HVTP set up or set down not only dampened the formality of the interview process, but it was also more convenient for both interviewer and interviewee, as it negated the need to carry out the two aspects of the study on separate visits. Therefore, the first interview, on day one, was conducted on the same day as the HVTP set up to maximise time and travel costs. Likewise, as the second part of the

interview took place on the last day of the procedure, the interview was conducted on the last day of the HVTP procedure.

The interviews were scheduled to last for 30 minutes but, in practice, they ranged in length from 13 to 41 minutes. The interviews were recorded using an Olympus VN-713 digital voice recorder. The patient chose the location for the interview within their home environment. No restrictions were made as to whether spouses/partners should attend the interview and this choice was left to individual patients. Where partners or spouses attended, a note was made and any contributions by the secondary participant were recorded and transcribed together with the primary interviewee.

### **5.1.3 Ethical and privacy considerations**

Ethical considerations are of great importance in qualitative methodology because researchers come very close to the participants' personal lives. To avoid disclosing the identities of the participants, the researchers are obliged to develop strategies to ensure confidentiality (Dahlgren, Emmelin, & Winkvist, 2007). With respect to ensuring participants' protection in the context of recording the interview, the primary ethical issues are the standard issues of informed consent, confidentiality and privacy, and participant burden and safety (Broyles et al., 2008).

Participants' rights, including the right to be informed about the study, the right to freely decide whether to participate in a study and the right to withdraw at any time without penalty, are important in a qualitative study (Capron, 1989). Informed consent was obtained from the patients involved and from their partner or spouse as required. The patient retained a copy of their signed consent. Ensuring that patients have sufficient information about a study can be difficult and sometimes patients do not actually read the information sheets provided; instead, they rely on verbal discussions to decide whether or not to participate (Newington & Metcalfe, 2014). In the present study, in addition to the already provided patient information, the researcher re-explained to the

patients the purpose of the research and the interview, and verbally confirmed patients' willingness to proceed with the interview.

To avoid disclosing the identities of the participants, the researchers are obliged to develop strategies to ensure confidentiality (Dahlgren et al., 2007). The convention of confidentiality is upheld as a means to protect the privacy of all persons, to build trust and rapport with study participants, and to maintain ethical standards and the integrity of the research process (Baez, 2002). Qualitative interviews are particularly prone to collecting data of a sensitive nature, which can cause anxiety and distress (Richards & Schwartz, 2002). To alleviate such anxiety, participants were reassured that the recorded interview would only be listened to by the researcher and that the transcripts would be entirely anonymised.

Sleep, in many cases, involves a shared environment (Rogojanski, Carney, & Monson, 2013). There is a particular issue with dyadic inquiry, whereby privacy is threatened when the interviewer probes into areas that at least one interviewee would prefer to keep private; since many interviews concern issues that are sensitive, this can make interviews emotionally intense and potentially harmful to both interviewees (Allmark, 2009). In recognition of the personal and intimate nature of interview data and the potential for unanticipated experiences that can evoke on-going concern (Dicicco-Bloom & Crabtree, 2006), in the present study, the patients were allowed to decide if they wished to have their bed partners to be present in the interview. The patients were also reassured that they were not obliged to discuss an issue if they felt uncomfortable.

As mentioned in earlier chapters, the study was reviewed and approved by the NRES Committee under reference number 14/LO/057), and registered with King's College Hospital Research and Development under registration number KCH14-121.

#### **5.1.4 Analysis**

The method of thematic analysis (Braun & Clarke, 2006) was used for this qualitative study analysis. It is one of the most common forms of analysis in qualitative research (Guest, MacQueen, & Namey.EE, 2012). It is a type of qualitative analysis used to analyse

classifications and present themes (patterns) that relate to the data (Alhojailan, 2012). Thematic analysis is essentially a method for identifying and analysing patterns in qualitative data (Clarke & Braun, 2013). It emphasises pinpointing, examining and recording patterns (or themes) within data (Braun & Clarke, 2006). Most researchers consider thematic analysis to be a very useful method in capturing the intricacies of meaning within a data set (Guest et al., 2012). It also offers a flexible tool that can provide a rich and detailed account of the data deductively (Alhojailan, 2012), and even in systematic analysis (J. Thomas & Harden, 2008). Indeed, the process is often very similar in all types of qualitative research in that it involves analysing transcripts, identifying themes within the data, and gathering together examples of those themes from the text (Burnard, Gill, Stewart, Treasure, & Chadwick, 2008). This form of analysis has a defined strategy that provides a clear link between the themes identified and the strategy for identifying them using a step-by-step guide in different phases, as described by Braun and Clarke (2006).

Thematic analysis often appeals to novice researchers who are working with narrative data for the first time with little or no experience of qualitative research (Braun & Clarke, 2006). Thematic analysis is performed through the process of coding in six phases to create established, meaningful patterns. These phases are as follows: familiarization with data, generating initial codes, searching for themes among codes, reviewing themes, defining and naming themes, and producing the final report (Braun & Clarke, 2006).

### **Phase 1: Familiarisation with the data**

This phase involves immersing oneself in the data so as to become familiar with the depth and breadth of the content of all aspects of the data. This immersion usually involves repeated reading of the data and reading the data in an active way, i.e., searching for meanings, patterns and so on. During this phase, taking notes or marking ideas for coding is helpful to allow the researcher to return to them in subsequent phases. This process is useful because as one becomes immersed in the data, the formation of ideas and the identification of possible patterns begin to take shape as one reads through.

In the present study, the researcher collected the data and so they approached the analysis with some prior knowledge of the data, and possibly some initial analytic interests or thoughts. In addition, the researcher listened to the individual interviews recorded several times. This helped to develop familiarity with the verbal accounts so that transcribing them would not introduce inaccuracies such as would be introduced, for instance, by adding or omitting punctuation that alters the flow or meaning of the data. Furthermore, in listening to the recordings several times, ideas or patterns that began to take shape by virtue of their recurrence, or that were striking in relation to the research acceptability of the HVTP procedure, were noted.

Verbatim transcription has been described as the word-for-word reproduction of verbal data, whereby the written words are an exact replication of the recorded words; therefore, the notion of a verbatim transcript is limited to a faithful reproduction of the aural record (Poland, 1995) although for some analyses, selected sentences, passages and paragraphs, or stories relevant to the research question or theory, may be all that are needed (Emerson, R.M, Fretz, & Shaw, 1995). Essentially, researchers undertake their first data reduction step when they decide what will be transcribed and what will be left out (Miles, 1994). However, at a minimum, it requires a rigorous and thorough orthographic transcript, i.e., a verbatim account of all verbal (and sometimes non-verbal [e.g., coughs]) utterances (Braun & Clarke, 2006). The level of detail necessary depends upon the aims of a research project, and there is a balance to be struck between readability and accuracy of a transcript (Poland, 1995). Representation of audible and visible data into written form is an interpretive process that involves making judgments; it is, therefore, the first step in analysing data and researchers need to decide which level of transcription detail is required for a particular project and how data are to be represented in written form (Bailey, 2008).

In the present study, the audio data was transcribed verbatim into a Word document. The verbatim transcription of research data was transcribed to capture the meanings and perceptions of the recorded interviews, as well as the context in which these were created. In addition, involuntary vocalizations, response/non-response tokens and non-verbal interactions were transcribed to add to the context and to offer clarity to the discussion or interview (Poland, 1995).

In the transcript, the interviewer's questions were typed in bold font to differentiate them from the interviewees' responses and for ease of reference. The Word document was checked for accuracy of orthographic components and compared to the researcher's written notes for any non-verbal cues highlighting emotional components such as hand gestures or facial expressions. At this stage, no linguistic corrections were made, but rather were left as the interviewer and interviewee said them; they were, however, included in the transcript and highlighted in a colour that was different from the interviewees' verbal responses. Deviations from the topic were also noted but not transcribed. For example, in one interview a cat came into the interview room and jumped on to the interviewee's lap; the interviewee then spent a couple of minutes talking to the cat or about the cat. In another interview, which was being held in the kitchen area, the interviewee interrupted the interview and offered the interviewer a cup of tea, and then talked excitedly about the kitchen that she had just had refurbished, costing a substantial amount of money.

The Word document of the data corpus was formatted so that each line was numbered. The researcher compared the transcripts with the notes from the interviews to determine how to organise the data. As an extension of the reorganisation of the transcribed data and for ease of reference, each line of transcribed data was copied and pasted onto an Excel spread sheet to form a row-column matrix, with each line of the data sitting on the first column of each row. The number of rows represented the number of lines of the transcript. The Excel sheet row-column matrix served two purposes: first, one could easily

use other columns (B, C, D, etc.) for codes and, secondly, the column-row matrix could be used for referencing during analysis, as necessary. A sample of this matrix layout is provided in Appendix 8.

### **Phase 2: Code generation**

Codes are defined as tags or labels for assigning units of meaning to the descriptive or inferential information compiled during a study and to ensure meaningful labels and codes are assigned to chunks of data, usually phrases, sentences, or paragraphs that are connected to a specific context or setting (Miles, 1994). Codes can either emerge from the raw data (data-driven) or they can grow from a specific project's research goals and questions (structural), with most codes being theory or data driven (Ryan & Bernard, 2003). Coding is the process of examining and organising the information contained in each interview and the whole dataset (Green et al., 2007). At this first level of coding, one is looking for distinct concepts and categories in the data, which will form the basic units of further coding. Coding reduces the amount of raw data to that which is relevant to the research question and breaks the data down to manageable sections (DeCuir-Gunby, Marshall, & AL, 2011).

During this phase of analysis, the researcher read the data actively and more slowly, thinking through the questions asked and the responses given, and paying attention to the follow-up questions and the responses. The search for and identification of common threads that extend across an entire interview or set of interviews was done within each interview and across all the interviews. It became clear that some words such as travelling, finding parking, separating from family and natural environment recurred in most interviews. This was an informal mode of word repetition analysis undertaken by simply reading the text (Ryan & Bernard, 2003), words or synonyms or phrases that tended to recur during the interviews, and which were then coded. These words and phrases were considered the initial units of analysis as they formed the most meaningful and productive units that are efficiently and reliably identifiable (Krippendorff, 1980). The

coding was either done line by line on the spreadsheet, or over several lines depending on the information the interviewee was conveying.

### **Phase 3: Searching for themes**

This phase involves collating codes into potential themes and gathering all data relevant to each potential theme. Themes can be considered as abstract, often fuzzy, constructs that investigators identify before, during and after data collection (Ryan & Bernard, 2003). A theme captures something important about the data in relation to the research question, and represents some level of patterned response or meaning within the data set (Braun & Clarke, 2006).

At this stage, the researcher went through the codes looking for key words or phrases and noting words surrounding the keywords. By combining the word repetition with key words in the context techniques (Luhn, 1960), words and phrases began to emerge with similarities. For instance, words such as travel, parking and childcare, etc., resonated with financial implications to the patients in having the HVTP procedure and, therefore, were collated under the heading 'monetary' as a main theme.

### **Phase 4: Reviewing themes**

This phase involves checking the data within themes for meaningful coherence and ensuring that there are clear and identifiable distinctions between themes. The collated extracts for each theme were read to check whether they appeared to form a coherent pattern.

Using constant comparison analysis of codes and associated text fragments in different interviews, a final set of codes and core themes were identified. The selection of codes was based on their frequency and dispersion within each individual patient's interviews and across the different patients' interviews.

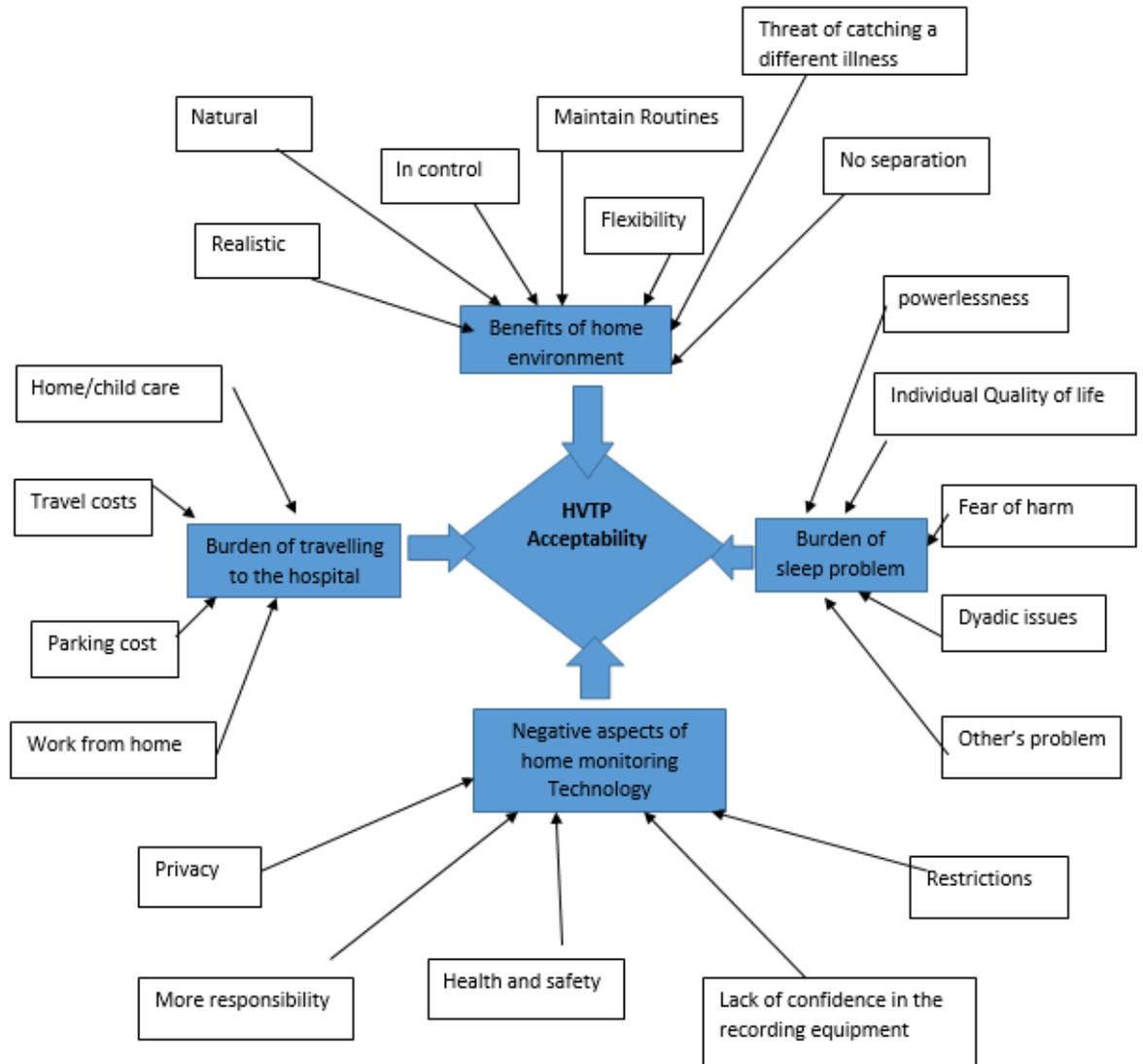
### **Phase 5: Defining and naming themes**

This phase involves identifying the subject of each theme, as well as determining what aspect of the data each theme captures. For each individual theme, in addition to identifying the 'story' that each theme tells, it was considered how each of them fitted into the broader overall 'story' of the data in relation to the research question. This process was conducted within each interview and across all interviews. Data saturation occurred after 24 interviews in 12 patients (two interview sessions per patient) with the majority of the codes appearing within the first fourteen interviews.

### **5.2 Results**

The thematic analysis process that was applied to the transcripts, i.e., data reduction, reconstruction and synthesis, elicited key concepts that emerged from the data culminating in the construction of a thematic map on three levels (Figure 19). This was the phase six of the thematic analysis.

Level one consisted of initial codes generated during phase two of thematic analysis. These were the most basic themes that were derived from the textual data in the coding phase, according to the underlying story they were telling. Level two consisted of themes developed in phases three to five of the thematic analysis. These represented clusters of significant summaries of Level one themes that reveal what is going on in the texts. They were the main themes identifying a story about the data in relation to the research question. Level three is the overarching theme representing an argument, or a position or an assertion, about a given issue or reality that the research question addresses.



**Figure 19** Thematic map showing themes and subthemes generated from analysis

The findings consist of four main themes emerging from the interviews of patients undergoing investigation for parasomnia, which could be considered as catalysts or barriers regarding the acceptability of HVTP as a viable clinical service. The definition of a main theme was that the topic recurred in more than one interview, or that the subject raised generated sufficient data to allow direct exploration of the research question in more detail. The quotations used from the interview transcripts were selected on the basis that they illustrate the most salient features of the theme or subtheme being described. The quotations also include an anonymised identifying number. Three of the

four main themes were catalysts and one of the four was a barrier to HVTP acceptability. The main themes and the associated subthemes are outlined in Table 26.

**Table 26 Main themes and subthemes**

<b><i>Burden of sleep problem</i></b>	
a.	Impact on the individual's quality of life
b.	Concern of potential or actual harm
c.	Effect on their bed partner's sleep
d.	Dyadic issues
e.	Family cohesion
f.	Frustration
<b><i>Benefits of home environment</i></b>	
a.	Self-determination and independence
b.	Natural reflection and representative.
c.	In control of their own environment
d.	Maintaining familiar routines
e.	Flexibility and convenience
f.	Separation from home and family
g.	Threat of catching a new illness
<b><i>Burden of travelling to the hospital</i></b>	
a.	Travelling time and cost
b.	Parking charges
c.	Home and child care
d.	Working from home

### ***Negative aspects of home monitoring technology***

- a. Privacy
- b. Recording equipment as a safety hazard
- c. Burden of recording equipment
- d. Restrictions and limited access to some activities
- e. Confidence with the recording equipment

The four main themes and their related subthemes are described and outlined in the sections that follow.

#### **5.2.1 Burden of sleep problem as a motivator for accepting HVTP**

During the interview, patients spoke of the effect the sleep problems had on their personal lives and those close to them. A recurring theme was the difficult associated with living with a sleep problem as a driving force for accepting anything that would help in finding a solution. Several subthemes emerged in relation to difficulties associated with their sleep problems.

##### **a. Impact on the individual's quality of life**

This subtheme refers to the impact that living with a sleep disorder had on the patients. Seven of the twelve patients interviewed mentioned that disturbed sleep had consequences of loss or reduced functioning during the day. When the events at night are so disruptive to sleep, an individual is unable to function well during the day. Some patients felt that this disruption had a massive impact on their quality of life, as the following excerpt from one patient highlights:

*It has affected every aspect of my life; massive, massive especially when you can't go to work, your life just gone down overnight [...] you just realise how much impact*

*it has on you [...] what you take for granted in life; and just relying, as I say on my family members to do things (pt04).*

Another patient narrated how disturbed sleep affected their working life, forcing the patient to develop some unusual coping mechanisms such as pulling over while driving to take a nap, or taking naps during their lunch hour at work:

*I was finding that I wake up for work at quarter to six, six whatever; I was obviously very tired and I found on several occasions during the day while driving, I would pull over [...] aah and lunch breaks, I would fall off to sleep (pt05).*

It appears from the interviews that problems associated with sleep reflect on how well individuals function during the day and, hence, affects an individual's quality of life.

#### **b. Concern of potential or actual harm occasioned by the sleep problem**

Parasomnia-type related behaviours can often be potentially harmful. Patients with RBD are particularly vulnerable to acting out their dreams, which can cause physical harm to the self or others. One patient narrated how his aberrant behaviour caused physical harm to his wife and himself:

*As the years go by, more and more obvious there is more wrong with me than that [...] I would kick my wife and punch my wife and pinch my wife, dive out bed, roll out of bed, head butt the wardrobe accidentally and head butt the light (pt03).*

#### **c. Effect on their bed partner's sleep**

This subtheme relates to the fact that sleep disturbance not only affects the individual, but also those close to them. This was mentioned by five of the twelve patients interviewed. There was considerable concern among these patients about the effects their sleep problems were having on their partners or spouses. One patient said:

*I want it sorted because I don't want to disturb my husband, he is my main carer; if he is disturbed of his sleep he has to look after the children and everything else, it's not fair for him to be exhausted (pt06).*

Another patient said that she was aware that her sleep disturbance affects her husband's sleep by waking him up:

*The awareness that my husband says I jerk a lot and it was waking him up quite a lot. So it is like when people snore. Obviously, I don't snore so much. Yaah waking him up by jerking (pt04).*

This subtheme shows that sleep disturbance is a problem not just for the sufferer, but also for the significant other or those closely associated with the sufferer.

#### **d. Family cohesion**

This subtheme relates to the emotional bonding that family members have toward one another. Sharing a bed is one way of enhancing this cohesion. Three patients talked about this aspect during the interview. From the discussions, it appeared that sleep disturbance resulted in a problem that forced a temporary relocation such as the patient or a bed partner moving to a different room to obtain restful sleep, as expressed by the following patients:

*As soon as I start nowadays [...] she moves into another bed [...] thinking that is just the start of it, there is more to come so she will move into another bedroom try to get a good night sleep (pt03).*

*I do have the opportunity, if I am awake a lot, to go and get into bed in the other room rather than disturb him (pt07).*

#### **e. Spouse's problem**

A rather interesting finding emerging from the interviews is that some patients were least concerned with the sleep problem for themselves but considered the sleep problem to be more of their spouse's than their own. Four patients who were interviewed did not consider the sleep disturbance to be a big problem for themselves, as the following patient explains:

*It has not affected me so much in that I still get my sleep, although it may be a broken sleep [...] ahh obviously, if I know I had done it, I must be aware of that very short period of time. So it has broken my sleep [...] the next day if have I had a bad night, I usually feel tired and lethargic knowing my sleep has been broken, but, in the main, only if my wife says something (pt03).*

And another patient, who explained that she was not even aware of her sleep disturbance and only heard of it from her husband, stated that:

*I don't know about them, it is my husband who tells me about them, body shakes 5-6 seconds sometimes up to 30 seconds. I feel dizzy in the morning dry mouth, nausea, happens 2-3 times a night (pt10).*

#### **f. Frustration**

One patient who was so frustrated by her sleep problem expressed her sleep problem as a battle. To her it was a constant struggle and she felt that she was in a constant battle that left her exhausted. Talking about her sleep disturbance, she explained that:

*It isn't proper sleep; I am just dipping in and out of the semi-dreaming state. It's weird. I can't describe it. And I'm just exhausted in the morning [...] so this is what I am battling with everyday [...] waking up tired and exhausted because I have not had a restful night so I am battling with that (pt12).*

### **5.2.2 Benefits of home environment for sleep studies**

#### **a. Self-determination and independence**

Patients value their self-determination and independence in dealing with their issues in ways that best suit them, even though sometimes it may not be the conventional way. One patient who had a sleep problem, which was complicated by the sequelae of a past stroke, had developed ways of coping in her own environment. This is best illustrated by a quotation from one patient who had an experience with hospital settings:

*I could do things; I got ways of doing things. Like one time they said you 'can't do that, you can't do that'. They were saying, they have their own way of doing things, the right way, but I got my easy way. I have been doing it for 20 years (pt02).*

**b. Natural reflection and representative**

The importance of having the test in a natural environment was frequently discussed in the interview with six out of the twelve patients interviewed discussing one aspect or other that related to the natural environment. There was awareness on the part of some patients that the kind of information obtained about sleep in a strange environment was not the same as what would be obtained in the home, which is the natural environment. One patient stated that:

*People in their own environment, they are likely to be more candid. I suspect the information obtained, obviously, I am not a scientist, but I think it is more representative of natural (pt08).*

**c. In control of their own environment**

This subtheme relates to limitations and compromises on the day-to-day activities that one must make to comply with hospital rules. Some patients said that some activities that they would do freely at home would be difficult in the hospital setting. For instance, discussing this aspect, one patient said:

*Yes, you know the phone can ring and you go and answer it and talk to somebody whereas if you was in the hospital you would not be able to do that [...] if you was awake in the night, you could turn the telly on if you wanted to, whereas if you was in the hospital it would be a radio and earphones [...] plus, you could have lots of lighting on and to sit and read if you decided in the middle of the night and in the hospital, you would not be able to do that (pt07).*

#### **d. Maintaining familiar routines**

Maintaining familiar routines is one of the subthemes that was frequently talked about during the interviews. Six of the twelve patients interviewed mentioned this issue as an important consideration. Although the words used by different interviewees varied, the messages were similar. One patient said:

*You can unplug yourself and go make a drink then come back to bed, sit and relax or go get a book if you thought of getting a book (pt07).*

And another patient said:

*Obviously, I can get up and do some things in the bedroom (pt04).*

#### **e. Flexibility and convenience**

This subtheme refers to the ease with which one is able to secure an appointment that suits them. One major problem in the hospital setting at King's College Hospital is the uncertainty of hospital bed availability for elective patients, including those suspected of parasomnias. This means that cancellation of an earlier arranged appointment can and does occur at short notice. Not only is there uncertainty of bed availability, but also negotiating an appointment becomes very difficult. For working patients, arranging time off work for the procedure is complicated by this uncertainty. Patients found it easier and less stressful when they could negotiate a time for HVTP, including a weekend that was most convenient for them. This is expressed in the excerpt below from one of the three patients that discusses this issue:

*It is matter of choice because, obviously, midweek people would be at work; obviously, my husband has a long weekend off every so often, so it worked so well those two days [...] yes, the timing is good (pt04).*

#### **f. Separation from home and family**

This theme refers to the fact that going to hospital overnight for any procedure necessitates separation from the family. Five of the twelve patients interviewed discussed

this and considered it an important factor in connection to having the test carried out in their home. Having the test at home meant they could do things they would normally do with their families, as expressed by the following excerpt from a mother of young children:

*I was quite lucky because the lead (wire) led to the lounge and I could sit on the couch [...] It's good because me and the children we play games, watch a video [...] so it's good cause I think if I had to go to hospital it would have caused them worry and stress because they always worry when I am away from home; children worry if I am ok [...] the fact that they could still see me and be around me, for me that was a big help (pt10).*

Similar sentiments are expressed by a grandparent whose grandchildren visits regularly:

*As I say, we have five grandchildren and the two smallest girls could pop in and see me whenever they wanted to; so eeh it hasn't really affected my life so much having it at home, whereas in the hospital it would have affected me quite a lot (pt08).*

#### **g. Threat of catching a different illness**

One elderly patient discussed this subtheme. It was, however, significant that the patient felt that going to the hospital carried an incidental risk of catching a different infection. This patient reflecting on the past said that:

*As a child, I can't remember being taken to the GP as the GP used to come home and that was pretty standard practice. One of the things is it helps to reduce infection (pt08).*

In summary, it appears from the interviews that the benefits associated with being in the home environment during the monitoring added weight to the acceptance of HVTP as a viable diagnostic method.

### **5.2.3 Burden of travelling to the hospital**

The burden of travelling to the hospital was a major theme discussed in six out of the twelve interviews conducted. The subthemes from this main theme revolved around time and cost, with travel time, travel costs, parking fees, homecare and working from home recurring frequently during the interviews.

#### **a. Travelling time and cost**

Travelling to the hospital is a subtheme that was directly mentioned by five of the twelve patients interviewed. Travelling to hospital required time and energy and incurred costs. Even when one eventually travels to hospital, there is often time spent waiting or looking around to find the place of appointment. The following quotations from two patients illustrates this subtheme:

*If I travelled to hospital, and stayed up for 2-3 nights and then my [...] wife travelled back during the daytime, it is time consuming; it is expensive (pt03).*

*[...] The logistics of travel, travel expenses unless there is reimbursement. As I said, for me, it is more convenient, obviously, because I am at home; I don't have to travel to the hospital, obviously, and there is a cost to incur as well (pt05).*

#### **b. Parking charges**

Like most hospitals, King's College Hospital was designed and built when car ownership and usage were significantly less than they are today. With an increase in health and social care activity, current capacity and management of car parking has become a problem with parking either not being available or incurring considerable expense on the part of the patient or those visiting the patient. This has a significant impact on the ability of patients to gain access to hospital facilities and meet their scheduled appointments. It was not surprising that the issue of parking came up when discussing the acceptability of HVTP. One patient who was interviewed with her husband said:

*First [...] parking; we do get charged two pound an hour to park [...] (Husband interjects) [...] another thing, me travelling down [...] to see her could never happen. Don't matter what happens in hospital, it's nice to be here at home. Lot easier doing it here than in the hospital (pt02 & spouse).*

**c. Home and child care**

When one is away from home, there is, at times, a need to arrange for certain basic domestic chores to be undertaken such as watering the plants, feeding one's pets, taking in deliveries, etc., but more importantly child care is sometimes required. Providing HVTP meant that such a requirement was not necessary, and patients found this arrangement very useful. One patient said that:

*[...] Having this done at home, you can still manage. If you are in hospital, you have to arrange for care. I think this works very well (pt08).*

**d. Working from home**

It is not uncommon, nowadays, for people to work from home. One patient considered that having HVTP allowed him to continue to work from home and his employer did not consider this as taking time off. According to him, having the test was more convenient. He said that:

*It is more convenient work-wise, because I can still work at home and not take days off work (pt05).*

In summary, traveling to the hospital has considerable weight in terms of travel time and cost; having the monitoring carried out at home alleviates this burden, thus, rendering home monitoring acceptable.

**5.2.4 Negative aspects of home monitoring technology**

**a. Privacy**

The HVTP required audio-visual recording as part of the procedure. The setup was arranged in such a way that the patient could see online what was being recorded.

Patients felt reassured by the fact that they could watch the recording online on the screen and adjust as needed, either by moving or covering the camera, or repositioning himself or herself. However, two patients commented on the fact that audio recording captured personal conversations, as is expressed by one patient saying:

*I must apologise for I just realised how many conversations I have had with different people on camera and I forgot I'm being filmed (pt04).*

**b. Recording equipment as a safety risk**

Various components of the HVTP recording system were assembled and maintained with the help of an in-house equipment development engineer from the unit at King's College Hospital. Despite best efforts during equipment assembly, sometimes the power cable and/or the telemetry cables inevitably crisscrossed across the room over certain areas that are in constant use by the patient or family members. Since there were constant movements around the room, trip hazards were a concern and the patients and other members of the family were required to ensure safety; this was sometimes subtly expressed in the interview, as can be seen by the following comments made by two patients:

*I suppose it was a little awkward to start with, getting used to having all these cables around you; but once you got used to it, it was not a problem at all (pt07).*

*[...] Having to watch not to trip on wires while moving (pt10).*

**c. Burden of recording equipment**

This subtheme refers to the fact that having the recording equipment was a burden to some of the patients. Four patients mentioned this in the interview. They felt that having the recording equipment at home made them feel as though they needed to bear some

responsibilities by taking care of the equipment and ensuring that all was working well. This meant that parents had to keep watch over children to ensure they did not interfere. For example, one patient said:

*On the other side, you have more responsibilities; you know [...] having to look after the equipment, having to see everything is working normally (pt10).*

#### **d. Restrictions and limited access to some activities**

Although the HVTP recording system offered some degree of freedom in movement, this was limited to about thirty feet. This restricted the patient in terms of how far they could go, and was occasionally described as an inconvenience and not entirely reflective of natural reality. Three of the twelve patients interviewed mentioned this as a negative aspect of monitoring from home. For example, one patient said:

Well being trapped obviously in a room is not very good [...] when I was so unwell [...] It would not have bothered me [...] You think, Oh my God, I'm going to sit in a room [...] I will keep myself occupied [...] I then, I said, you know [...] it does not give a true reflection of your day because in a day you do lots and lots of things and being in a room actually you are not going to be your normal (pt04).

#### **e. Confidence with the recording of equipment**

This subtheme refers to the uncertainty of whether the information obtained in the home recording would be of good quality. Four patients mentioned this during interviews. One patient stated:

*[...] and if the equipment does the job, then it does the job [...] It has been interesting to see how sensitive the equipment is [...] when you ask me to*

*move this leg, that leg [...] it gives me confidence that it is recording what it is meant to record (pt05).*

Another patient was more direct, making reference to what was being recorded at home compared with what would be recorded in the hospital:

*[...] but accuracy, if you know what I mean, and whether it is as good as in the hospital (pt10).*

### **5.3 Discussion**

Patient acceptability, which is a pillar of quality in healthcare, is defined as conformity to the wishes, desires, and expectations of patients and responsible members of their families (Donabedian, 2003). It can be considered the degree to which a service meets or exceeds the expectations of informed consumers and a key to patient centred care. It is important in determining how well an intervention will be received by the target population, and the extent to which the new intervention or its components might meet the needs of the target population and organisational setting (Ayala & Elder, 2011). Acceptability is closely linked to the level of patient involvement, which refers to approaches that engage individual patients in the management of their health and healthcare, and in the decisions, that are made in the course of it.

In 2005, a survey of the general American population indicated that being involved in decisions about their condition and treatment was the most important factor for accepting treatment (Levinson, Kao, Kuby, & Thisted, 2005). One of the most common sources of patient dissatisfaction is not feeling properly informed about (and involved in) their treatment (Coulter, Parsons, & Askham, 2008). It is, therefore, important to consider patients' desires and expectations about what should occur in the health care setting.

There are different ways of assessing patient expectations, experience and satisfaction; one way of doing this is by employing a qualitative methodology. Qualitative methodology is valuable in helping to understand meanings and processes, and uncovering issues about healthcare interventions such as HVTP that have not been

previously addressed. Using qualitative methodology, the present study has explored issues related to HVTP as a diagnostic intervention. The one-to-one interview in the present study highlighted some important issues that interplay an array of social factors that influence the acceptability of HVTP. This methodology allowed themes to emerge directly from the patients' own voices, giving a more accurate representation of their experiences without the constraint of predetermined influences.

The results of this study show that the acceptability of HVTP is based on a complex and multifaceted appraisal of elements, which incorporates potentially positive and negative experiences and perceptions. The results show that the sleep problem itself, the convenience of being in their own environment, the perceived monetary gains, and the complexity of the technology all had some influence on patients' acceptance of HVTP, as discussed in the sections that follow.

### **5.3.1 HVTP process as a family issue**

Sleep is embedded in the social context of everyday life, especially in the household and family. In some cases, sleeping takes place in a shared environment. The quality of one person's sleep is vulnerable to disturbance by others within the same sleeping environment. Most adults sleep with a partner and sleep problems and relationship problems co-occur for some. Given that the marital relationship is the primary social context for most adults, and that most married adults sleep with their spouse, sleep disturbances may have important implications for marriage. Unless one lives alone, sleep problems are not likely to be solely an individual matter, but rather a dyadic problem. A study by Strawbridge, Shema, and Roberts (2004) suggested that spouses' sleep problems negatively impact partners' health and wellbeing. Some patients confessed that they were unaware or hardly affected by the sleep problem themselves and that they have only taken it seriously because of their partners. The effect of dealing with this complex problem in the family, on the part of a long-suffering patient and their partner, make a search for a solution a priority.

There was, therefore, unsurprising yearning among the patients and their partners to get to the root of the problem; for them, the diagnostic process was a major step towards this goal. Thus, many patients and their partners welcomed HVTP, not just because it was part of the search for the solution, but also because it also allowed other members of the family to have a direct involvement in this diagnostic process. It has been suggested that including partners as active participants in sleep medicine interventions may improve compliance and the cost-effectiveness of sleep treatments (Troxel, Robles, Hall, & Buysse, 2007). According to Matwiyoff and Lee-Chiong (2010), the cornerstone of treatment for all parasomnias is adequate patient and bed partner education; furthermore, bed-partners play a prominent role in the diagnosis of sleep disorders, including obstructive sleep apnoea as 'a disease of listeners'. The HVTP model provides such a forum where the patients and the partners or spouses are part of the diagnostic process.

### **5.3.2 HVTP and territorial roles**

Home for most people is where one is free to be oneself and do whatever one wishes. A person may be very proud of his or her expertise in certain types of home related activities such as cooking, sewing, mechanics, etc. Even more commonly, people gain much satisfaction from other roles such as that of a mother, father, teacher or any number of other things. Separation from this environment because of illness related activities might cause suffering if one thinks their expertise may be threatened; thus, a person might see illness as a threat to that role.

Regarding laboratory video telemetry polysomnography (LVTP), this necessitates admission to hospital for one or two nights. Admission to a hospital almost always creates a threat to the territorial role because it temporarily interferes with a person's ability to demonstrate their expertise or role function in the respective areas. Patients talked of the relief they felt in knowing that they could still have the test performed at home, without threatening their territorial expertise or roles.

### **5.3.3 Control and self determination**

The hospital setting creates a depersonalising environment that forces the patient to relinquish control over his or her daily existence (Taylor, 1979). The depersonalising of the patient in the hospital occurs through several means including hospital routines and procedures. Hospital admission causes an individual to forfeit control over virtually every task he or she customarily performs. This loss of control may leave the patients with feelings of anxiety, powerlessness, overdependence, helplessness and loss of independence. Wilson (1963) expressed this well saying,

“As he strips off his clothing so he strips off, too, his favoured costume of social roles, his favoured style, his customary identity in the world. He becomes subject to a time schedule and a pattern of activity not of his own making” ((Wilson, 1963).

Hospitalisation, therefore, takes away one’s control and self-determination. The HVTP model was attractive to the patient because the model eliminates these hospital effects. In the home, patients can make choices without any external influence and interference regarding what they do during the procedure. In the home, they can make home-life choices and decisions based on their own preferences and interests. They can determine and regulate their own actions and be self-directing including in activities such as smoking or drinking, which are restricted in a hospital environment.

### **5.3.4 True reflection of reality of natural sleep**

Sleep studies tend to be conducted in three traditional environments: the sleep laboratory, a hospital room or the home. While sleep studies in a clinical sleep centre can evaluate an individual’s sleep quality effectively, these evaluations do not occur in individuals’ actual homes. Thus, they cannot directly identify environmental factors that might contribute to sleep disturbances or reduced sleep quality. The bedroom environment can have a significant impact on the quality of a person’s sleep. Environmental factors can be a major cause of poor sleep quality and interrupted sleep, and familiar environments have a great impact on sleep, especially regarding daily routines. Patients tend to follow a specific bedtime routine, and are often concerned that they would not be able to sleep at all in the sleep laboratory. In sleep laboratories,

although efforts are made to minimise these effects, there are still considerable limitations. The advantage of home based study is the fact that the patients are likely to be more comfortable sleeping at home than in a laboratory, and perhaps a clearer reflection of what their sleeping patterns look like can be attained. Patients interviewed after undergoing the HVTP process considered HVTP to be a positive experience regarding their perception as to how well they slept.

### **5.3.5 Economical considerations**

When a patient is hospitalised for any reason, including sleep disorder assessments, family members assume increased responsibilities and often suffer monetary losses. Travel time, travel costs and parking charges were repeatedly cited by patients as representing the difficulties encountered by the patients in trying to reach the hospital for investigations. Most patients attending hospital appointments as patients or visitors, or simply accompanying the patient, use cars. Potential difficulties in terms of travel costs, time spent waiting for an available parking space and finding the correct change for parking charges were perceived as stressful and negative experiences for patients. Expense-related comments also touched on the support required from an administrative perspective. For instance, being away from home for some would require special home care arrangements in the form of childcare, home sitting, pet sitting, etc. As such arrangements or adjustments were not necessary during the HVTP process, the patients found HVTP acceptable.

### **5.3.6 HVTP and territorial encroachment**

Human beings exist in a dynamic relationship with the environment. One aspect of this dynamic relationship is territoriality; that is, the sense of having control over an area of space (Proshansky, Ittelson, & Rivlin, 1970). One knows that being in one's own home territory gives an advantage in that a person feels more secure and more in control. In one's own territory, a person may feel free to ask questions, resist a suggested course of action or hold out for what one wants, while the same person outside their territory may be meek, submissive and withdrawn. For the need of territoriality to be fully met, the person must be in control of some space, able to establish rules for the space and to

defend it against invasion or misuse by others, and their right to do those things must be acknowledged by others.

Home territory is one area where selected members of an institution, most commonly a family, have relatively larger freedom and control. The home also reflects the individual's identity, tastes and values and maximises his or her freedom of choice. The HVTP procedure necessitates not only entering someone's home environment, thus potentially violating territoriality, but the procedure is also carried in the patient's bedroom, which encroaches on someone's personal space and privacy. For most patients interviewed, acceptance of HVTP, a procedure that violates territoriality and infringes on personal space and privacy, was an act of balancing the need to get to the root of a problem that had an immense impact on the individual and family life against the inconvenience of territorial encroachment. They just wanted their problem to be sorted and they viewed the HVTP procedure as acceptable on the basis of this need.

### **5.3.7. Impact of HVTP recording on privacy**

Digital audio and video recordings introduce a novel possibility for applying diagnostic monitoring technology in the home environment. While technology is becoming more sophisticated, the monitoring nature of these devices may prove to be an infringement of patients' rights to privacy. As a person's private and personal space, there is a different psychological dynamic operating in the home environment than in an institutional facility (Hensel, Demir, & Courtney, 2006).

In HVTP, confidentiality and privacy remains a concern and must always be considered. Not only are HVTP records bio-physiological data, but they are also continuous audio-visual data. Using live audio and video streaming in this manner, however, raises privacy concerns. The use of video recording technology also creates a sense of restriction and encroachment of privacy. Monitoring and clinical interventions of this nature may intrude on a person's free choice, decision-making, privacy and autonomy. For instance, in ordinary family conversations, awareness of audio-visual monitoring may make a person feel as though they cannot speak freely. This kind of psychological obtrusiveness

manifests itself in feelings such as anxiety, worry or frustration that are associated with the technology.

Medical technology, once used exclusively in hospitals, is now available for use in the home. With access to home monitoring devices, computers and communication networks, patients can become more active in their own health care. Technology should not overwhelm the patient and every effort should be made to make them as unobtrusive as possible. With HVTP, physical obtrusiveness is physically experienced such as with wearable technology devices that may be perceived as uncomfortable by the user. By allowing multiple electrodes and biosensors to be attached to his or her body, one must entrust his or her body to the clinical practitioner who, for all intents and purposes, is a stranger. This obtrusiveness is, however, not unique to HVTP and is also experienced in the hospital laboratory environment.

The main issue is to improve patient experience by providing the appropriate and fully executed technology to sustain the objective in a transparent manner with regard to patient privacy. Implications for practice include technological design and evaluation informed by appropriate research. Invasions of privacy are often cited as examples of technology-related obtrusiveness (Leino-Kilpi et al., 2001). Technology designers need to be mindful of the balance between intrusiveness and usefulness in monitoring systems. A focus group of seniors on the acceptability of monitoring technology indicated that they are concerned primarily about user friendliness of the technology, the lack of human contact and the need for specialised training (Demiris et al., 2004). In another study, Caine, Fisk, and Rogers (2006) looked at privacy preferences regarding video monitoring in older adults; this study indicated that privacy should be respected for performing specific activities or in certain rooms of a home.

Obtrusiveness can range from what some may see as inconveniences (e.g., interference with daily activities), to potentially deeper concerns (e.g., symbol of loss of independence (Hensel et al., 2006). In the present study, the recording system provided a visible online

display of the recording and it was possible, when necessary, for the patients to change sitting positions or move the camera away or adjust the equipment trolley. This provided the patient with a sense of control over what was being recorded by the video camera. This online feedback was found to be a useful feature, not only in dealing with privacy concerns, but it also served as an assurance to the patients that the recording system was working well. It was, however, not possible to obscure sound recording and patients were fully aware that sound was still being recorded even when they obscured the video. Despite this, sound recording remained a concern for some patients, as they indicated forgetting being recorded and having conversations that they would rather be private.

## **5.4 Limitations of the study**

### **5.4.1 Numbers and diversity of participants**

The study was limited by a small number of patients interviewed. However, the coding for each theme was consistent across most of the sample with data saturation occurring within 24 interviews with 12 patients. A further limitation was the lack of integration of views from other potential players. In this study, acceptability was explored only from the patients' point of view; however, HVTP is a process that involves teamwork and, potentially, the views of different members of the team could be valuable in future research in determining overall acceptability of the process. The interpreting clinicians, other clinical physiologists involved or helping in performing these tests in the patients' home, and the treating clinicians referring these patients for the procedure may have something to contribute regarding acceptability. Overall acceptability, therefore, should not be viewed only from the patients' point of view, but also from the other players involved in the process.

### **5.4.2 Credibility**

The purpose of qualitative research is to describe or understand the phenomena of interest from the participants' perspective. The participants are, therefore, the only ones who can legitimately judge the credibility of the results. Respondents' validation, including inviting participants to comment on the interview transcript and whether the

final themes and concepts adequately reflect the phenomena being investigated, would add credibility to the results. This validation was, however, not carried out in this study due to practical reasons and would be worth considering in future research.

## **5.5 Conclusion**

To fully understand an individual's sleep problem, it may be desirable that sleep should be studied from an ecological perspective, as a dyadic rather than an individual phenomenon. A dyadic approach in the assessment and management of sleep problems is a promising method of exploring concurrent sleep disturbances and establishing associations between sleep and sleep-impairing factors that may co-vary in the members of the dyad. Evaluating sleep and sleep disorders from a dyadic perspective is both important and more representative of the individual's sleep behaviour. The home is the ideal environment for such study. HVTP is a promising model for this kind of clinical assessment. However, whether or not this model is acceptable to the patients is unclear and has not been fully addressed before and hence justifying the current study.

Although patients are concerned with the clinical aspect of care, they mostly tend to form their opinions about service quality based on their assessment of non-clinical aspects of care such as the availability and accessibility of facilities and amenities, security in and around the facility, clean and comfortable rooms, privacy, tasty meals, comfortable clothes and a quiet and attractive environment (Mosadeghrad, 2012). The way the patients experience health services is an important component of the quality of care. Patient experience is defined as the sum of all interaction, shaped by an organisations culture that influence the patients' perceptions across the continuum of care (Wolf, Niederhauser, Marshburn, & LaVela, 2014). Therefore, measuring patient experience is not only important as a guide to service improvement, but also because patients' experiences of care are largely intrinsically linked to clinical outcomes and costs (Riskind, Fossey, & Brill, 2011). The core of patients' acceptance of a procedure or treatment is not just the acceptance itself, but also the process of reaching such a decision. An important consideration in such decision-making is the degree to which the patient feels in control. Health professionals carrying out clinical procedures in patients' homes must be acutely

aware of the concept of territoriality in human behaviour as they attend to the medical, physical and psychological needs of their clients.

Study of acceptability is, therefore, an important consideration because it will impact on the take-up of the type of diagnostic intervention offered and the compliance or willingness to see the course through. The findings in this study provide initial important insights into key elements related to the acceptability of HVTP as a clinical diagnostic procedure for patients suffering from parasomnias. The results show that patients' acceptance of HVTP incorporates both positive and negative experiences and perceptions.

The impact of potential sleep parasomnia behaviour on the individual and immediate family, environmental factors, economic considerations and technical related issues appear to be strong drivers in accepting HVTP, but they are not necessarily the only ones. Overall, HVTP was perceived positively and was acceptable to the patients and their family members.

## **Chapter 6: Cost aspects of home video telemetry polysomnography (HVTP)**

### **6.1 Overview of HVTP costing**

National Health Service (NHS) resources are limited while the demand for health care continues to increase at a steady speed. In some cases, demand outstrips capacity raising concerns regarding resource management. It is, therefore, necessary to maximise the use of available resources. Inevitably, the utilisation of resources devoted to hospital services, including sleep studies, are increasingly subject to rigorous scrutiny and a delicate balance between demand and capacity (Frankel, Ebrahim, & Davey Smith, 2000). Increasing capacity would mean more resources, but this is often not a feasible option. As resources are scarce, in terms of time, staff, facilities, equipment and knowledge, an active consideration of the factors involved in the allocation of healthcare resources for one use instead of another must not only be made, but also regularly reviewed. In sleep medicine, increasing demand for sleep studies cannot always be matched with increasing capacity in terms of more staff and sleep study facilities. Therefore, other strategies for increasing efficiency are required. One potential alternative in sleep medicine is a technical one, in the sense that technological advancement makes transformation of the comprehensive VTP sleep study processes possible. This is not only possible within the hospital laboratory environment, but also potentially in patients' own homes. In particular, home sleep studies are one way in which technological advancement can be used to help alleviate the demand and capacity mismatch by freeing up hospital beds and potentially reducing costs. However, the peripatetic nature of delivering this kind of home service is complex and requires consideration of feasibility in terms of cost implications for a viable clinical service.

Cost information is an important part of the decision making when a choice exists between different interventions, in this case HVTP verses hospital based LVTP. LVTP is an expensive labour-intensive procedure and it is assumed that HVTP would help to cut the cost. At present, it is not clear how much it would generally cost to perform comprehensive HVTP. It is also unclear what cost elements are involved in carrying out this procedure in patients' home and, thus, raises the need for cost analysis of this kind of service.

### **6.1.1. Objectives**

This cost analysis study was undertaken as part of a feasibility study looking at quality, cost and acceptability of HVTP as part of the clinical neurophysiology patient care delivery service improvement initiative at King's College Hospital. The term HVTP is used to describe this complex diagnostic procedure for assessing patients under investigation for a potential parasomnia sleep disorder. This cost strand of the mixed method feasibility study was carried out to outline the process and issues involved; it also illustrates the various cost elements in undertaking complex multi-parameter recordings in the patients' own homes and compares this with tariffs of laboratory based studies of similar complexity within the hospital setting at King's.

The accrued information in this feasibility study will be valuable in informing a further effectiveness study to establish whether, overall, there is cost minimisation in performing full HVTP. This undertaking requires a clinical costing method that can obtain accurate patient costs to allow resource usage to be identified for individual patients undergoing HVTP. Clinical costing is the process of calculating the costs associated with delivering care to individual patients.

### **6.1.2 Clinical verses research related costs**

As this was a research project, cost elements were derived from both research related activities and patient care related activities. It is important to consider and separate research related cost from the intervention or patient care related costs. In this study, the patient care related costs were intervention related costs, which were cost elements associated with carrying out HVTP. These interventional costs would continue to be incurred if the patient care service in question continued to be provided after the research study was concluded. Conversely, the research related cost elements, which were the additional costs associated with the research, would end once the research study in question had concluded, even if the interventional patient care involved continued to be provided.

In this study, only the HVTP related costs were evaluated. By making this distinction at the outset, it was easier to articulate the method of costing, identify the perspective, clarify the type of costs that need to be measured and establish the time span.

### **6.1.3 Cost perspective**

To estimate the total costs of a particular health service, it is important to not only identify all the relevant costs, but also those who bear these costs. The perspective or viewpoint determines the cost components to be measured. The perspective indicates whose costs and benefits are incorporated in the analysis (Elliott & Payne, 2005). Two common perspectives are the societal perspective, in which all costs and benefits are captured, and the perspective of the provider of the health care services, where only actual specific costs incurred in providing a particular service are considered. The costing for this study was carried out from the perspective of the healthcare service provider. The reason for adopting the perspective of the healthcare provider was to help determine the specific types of cost elements that should be considered in the process of the HVTP procedure and to allow comparison with similar elements derived for hospital based VTP in a later effectiveness study.

### **6.1.4 Cost analysis time span**

In costing studies, it is important to specify the time during which the study has taken place and the time period that the unit costs refer to. This is important for two main reasons: First, the unit costs can be updated or adjusted if necessary; and second, the effect of changes in cost over time, due to technological advances and inflation or both, can be assessed. The costing in this study must, therefore, be considered in the context of 2014/2015, the time frame in which the study was carried out.

### **6.1.5 Clarification of the cost object in this study**

In cost analysis, the cost object is an item for which there is a need to separately estimate cost (Mogyorosy & Smith, 2005). In a broad sense, the cost object can be an organisational division, a function, task, product, service, or a customer. The choice and definition of health services (cost objects) substantially determines the type of cost information needed, as well

as the measurement and valuation method of the resource used. For the purpose of the present study, the HVTP procedure was considered to be the cost object. The costing of HVTP was defined as a measure of the value of all resources used to provide an interpretable home recorded HVTP data and the related clinical report.

## **6.2 Materials and methods**

A challenging element of cost analysis is establishing the proper measurement of costs. This is very much the case when the costing involves complex and multiple aspects. Approaches to costing methods vary widely. At one end of the spectrum, there is the direct measurement of patient-specific resource utilisation, frequently called the bottom up-micro costing method (Mogyorosz & Smith, 2005). At the other end of the spectrum is the indirect, top-down gross costing method, which estimates resource utilisation and costs by assigning an average figure based on available information from administrative databases (Wordsworth, Ludbrook, Caskey, & Macleod, 2005). In gross costing analysis, cost components are defined at a highly-aggregated level (e.g., inpatient days only), whereas in micro costing all relevant cost components are defined at the most detailed level. The choice of costing methods is usually considered by balancing the value of addressing the specific research question as accurately as possible against using a more intensive costing approach.

Costing activities at the patient level is a powerful tool in informing the efficient redesign of pathways, the elimination of waste and the reduction of costs. The level of detail is determined by two important considerations. The first consideration is the identification of cost components. Gross costing methods, where resource utilisation is estimated, or micro costing methods, where specific resource utilisation is identified, can identify the cost components. The second consideration is related to the valuation of the cost components. In the top-down approach, average unit costs per patient are obtained by separating out the relevant costs from comprehensive sources. In the bottom-up approach, patient specific unit costs are obtained by identifying direct resources for the patient. This is best achieved by the bottom-up micro costing method (Tan, Rutten, van Ineveld, Redekop, & Hakkaart-van Roijen, 2009), as illustrated in Table 27.

**Table 27 The level of accuracy at the identification and valuation of cost components - modified from Tan et al. (2009)**

		Identify cost components	Valuation cost components	
Direct	**	Micro costing (identifying specific resources use)	Bottom-up (identifying resource use directly)	**
Indirect	*	Gross costing (estimated resource use)	Top-bottom (total expenditure is distributed down)	*

\*\*\*\* A combination of micro costing and bottom up approach

\*\* A combination of gross costing and top bottom approach

Table 27 shows different combinations of costing methods and their level of accuracy. It shows that a combination of bottom-up and micro costing (denoted with four stars) is the most accurate, but it is also the most difficult and time consuming. Conversely, a combination of top-bottom and gross costing (denoted with two stars) is the least accurate, but it is also easier to carry out and less time consuming. The other two combinations of micro costing with top-bottom, and bottom-up with gross costing, with three stars are fairly accurate.

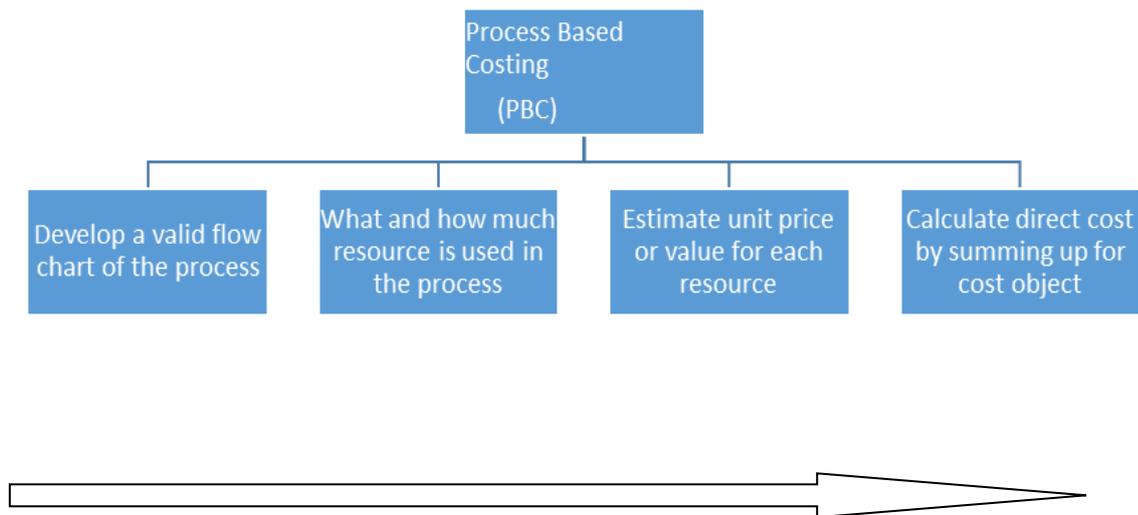
Although bottom-up micro costing is considered to result in the most accurate cost estimate for healthcare services, because all items are identified and valued at the most detailed level by accounting for every bit of activity involved in achieving the cost objective, for practical and resource reasons, the present feasibility project adopted a mixed costing method (Baboolal et al., 2008); (Hendriks et al., 2014); (Cunnama et al., 2016)). The choice of this method was informed by the fact that HVTP is a new service for which data or unit cost

estimates are not available and, hence, requires a detailed direct costs measurement, while simultaneously recognising that detailed information might not be feasible for some indirect cost units. This mixed costing method allowed flexibility to apply bottom-up micro costing to specific activities, which accounted for a large share of total costs and for those activities whose data collection was reasonably feasible; on the other hand, for those general activities whose data collection are difficult, the less accurate top-down gross costing could be applied. The mixed model allowed the prioritisation of the cost measurement towards the study objectives and to decide where there would be reliance on direct cost measurement (micro-costing), and where computer based databases (gross-costing) would be used.

Direct costs represent the value of resources used in a process, while indirect costs, which are sometimes called overhead costs, represent the value of resources that cannot be linked to a particular process. Direct costs are a key concern for this feasibility study since these direct costs can be controlled at the departmental level, making them the basis of quality improvement efforts. Furthermore, most techniques for allocating overhead costs depend on estimates of direct costs (Kaplan & Cooper, 1998); hence, obtaining accurate direct cost for HVTP would allow a more accurate estimation of the indirect costs.

### **6.2.1 Process costing method**

Lean production is a well-established management concept in many manufacturing organisations (Shah & Ward, 2007). A similar approach to deliver higher health care quality at lower costs would be invaluable in the health care services. A flow model may be used as a measurement framework to capture changes towards lean thinking in health care (Kollberg, Dahlgaard, & Brehmer, 2007). The present study adopted a flow model using Process Based Costing (PBC). The PBC been proposed as a simple inexpensive costing model with a clearly defined process flow chart based on participant interviews (Lee et al., 2003). This model proposes four stages (Figure 20):



**Figure 20 An overview of process-based costing, adapted from Lee et al. (2003)**

i. Develop a valid flow chart of the process

The first step involves identifying transactions required in the whole process. A transaction was preferred to an activity as it incorporated all other resources required: in addition, micro costing was used instead of gross costing. Once all the transactions are identified, a flow chart is developed specifying all the steps required to produce the final cost object.

ii. What and how many resources are used in the process?

Step two is the most difficult step. It involves quantifying resources used by measuring all resources required and quantifying them into natural units such as time, weight, volume numbers, etc.

iii. Estimate unit price or value for each resource

Step three involves establishing the value of the resources used in the process. This is done by directly converting the natural units to currencies or monetary equivalents, e.g., time spent by staff converted to equivalent pay, volume of consumables spent into unit price etc.

iv. Calculate direct cost by summing up for cost object

Step four is a mathematical process and involves collating costs on all transactions. These are summed up to get the total cost.

### **6.2.2 Resources identification**

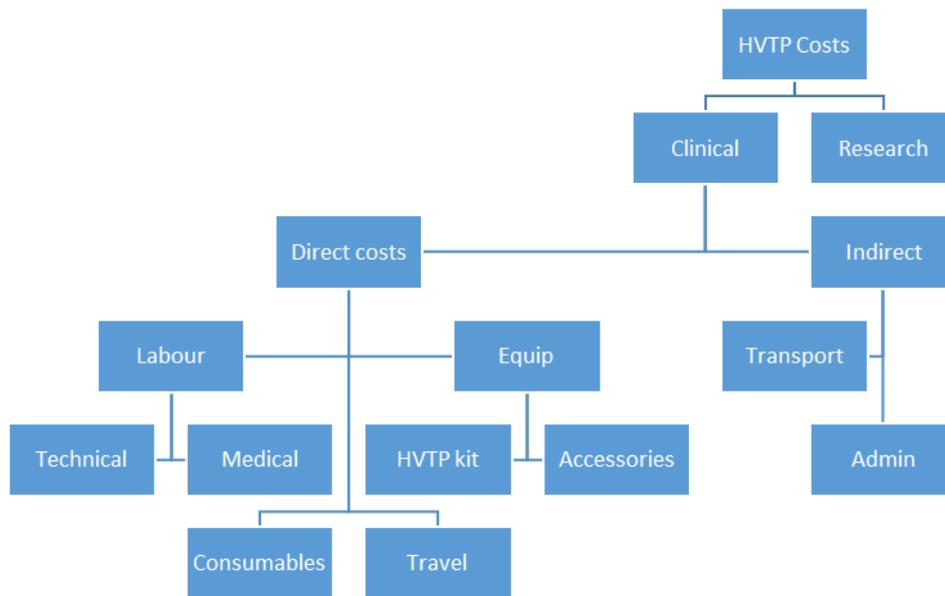
An important step in any type of costing methodology is the identification of the resource items that need capturing in the analysis. One useful way to do this is creating a process map, as proposed in the model mentioned in the previous section. A process map is a pictorial representation showing all the activities and steps of a process. This can be done by mapping out a workflow of the pathway of interest so that at each stage the likely resource items incurred can be identified and categorised by the type of resource. The advantage of such documentation is that it allows precise definition of each activity. This, in turn, enables the resources consumed, such as time and efforts of professional and technical staff, consumables and equipment usage, to be more accurately quantified. This provides a basis for identifying the origin of the costs of an activity and for determining their relevance to the underlying objective of the process.

The HVTP procedure, as a cost object, can be considered as a process with an identifiable beginning and end. The beginning is marked by receiving the referral requesting the sleep study and the end is marked by dispatching the report to the referring clinician after the test has been completed. In this study, the HVTP process was partitioned into discrete elements termed transactions. A transaction was defined as any patient-related task requiring resources in the context of performing an HVTP study. By prospective tracking of the HVTP process from the time the referral requesting the procedure is received to the time a report of the outcome of the procedure is dispatched, a comprehensive list of activities involved during HVTP was compiled for each study using participant interviews and self-recorded diaries. Careful consideration was taken to ensure that sufficient detail was included in those resource items that were likely to form the largest components of the total cost, which are usually regarded as cost drivers. From this data, a detailed flowchart or flow list of the HVTP process was created (Table 28).

**Table 28 Process flow chart showing activities involved during HVTP**

	HVTP process flow chart
1	Referral processing/registration
2	Referral review/vetting
3	Phone interview/assessment
4	Invitation/information leaflet
5	Processing appointment
6	Obtaining informed consent
7	Return journey day 1
8	Setting patient and recording
9	Return journey day 2
10	Record optimisation/retrieval
11	Night 1 processing and analysis
12	Return journey day 3
13	Disconnection/set down/ data retrieval
14	Night 2 processing and analysis
15	Clinical consultation/history
16	Clinical reporting
17	Report processing

The identified activities were grouped according to their degree of similarity and function, so as to mirror the objectives of the costing system (Figure 21). Activities represent all the actions performed to convert and to support the conversion of materials, labour, technology and other resources into cost items. Initially, the activities were classified as either relating to direct or indirect costs. The direct costs are costs for which there is a direct, causal relationship between the considered cost and the cost object. They have a clear quantifiable link with the cost object and can, thus, be allocated directly to it. On the other hand, indirect costs do not have such a clear link with the cost object.



**Figure 21 Classifications of HVTP cost items**

### 6.2.3 Resources quantification

Using a bottom-up approach, detailed information on each resource and activity associated with HVTP was recorded onto a tabulated worksheet as it was performed. Each distinct resource item and associated activities constituted a transaction. A transaction can be defined as any exchange between two parties that constitutes part of a medical intervention (Stiles & Mick, 1997). Transactions were coded as caregiving transactions or coordinating transactions depending on the level of patient care involvement (Henry, Ness, Stiles, Shintani, & Dittus, 2007). Transactions involving direct patient care were considered as care giving transactions and all other transactions as coordinating transactions. The resources required for those transactions were identified respectively. Table 29 shows the classification of HVTP transactions and the type of activities involved in that transaction.

**Table 29 Classification of HVTP transactions showing the type of activity and materials involved**

	Transaction	Code	Labour	Equipment	Consumables	Transport
1	Referral processing/registration	CT	Yes	Yes	Yes	No
2	Referral review/vetting	CGT	Yes	Yes	Yes	No
3	Phone interview/ assessment	CGT	Yes	Yes	Yes	No
4	Invitation/information leaflet	CT	Yes	Yes	Yes	No
5	Processing appointment	CT	Yes	Yes	Yes	No
6	Obtaining informed consent	CGT	Yes	No	Yes	No
7	Return journey day 1 (Travel)	CT	Yes	Yes	No	Yes
8	Setting patient and recording	CGT	Yes	Yes	Yes	No
9	Return Journey day 2 (Travel)	CT	Yes	Yes	No	Yes
10	Record optimization/retrieval	CGT	Yes	Yes	Yes	No
11	Night 1 processing and analysis	CGT	Yes	Yes	Yes	No
12	Return Journey day 3 (travel)	CT	Yes	Yes	No	Yes
13	Disconnection/set down/data retrieval	CGT	Yes	Yes	Yes	Yes
14	Night 2 processing and analysis	CGT	Yes	Yes	Yes	No
15	Clinical consultation	CGT	Yes	Yes	Yes	No
16	Clinical reporting	CGT	Yes	Yes	Yes	No
17	Report processing	CT	Yes	Yes	Yes	No

Key: CT-coordinating transactions which are more indirect cost elements; CGT-care giving transactions which are more direct cost elements.

Each transaction was considered to involve different resources including labour, equipment, consumables and transport. All the transactions listed, including coordinating transactions, were patient related with a link to the cost object and, hence, included in the analysis. Caregiving transactions included travel, labour, equipment and consumables; the coordinating transaction included transport and administrative related costs.

The cost of each transaction required to contribute to the cost object was measured by quantifying the resource utilised. Natural units were used for measurement. The natural units were in the form of time measured in minutes, distance travelled in miles and quantities of resources consumed in terms their respective units of measurements such as weight, volume or actual number of items.

#### **6.2.4 Attaching monetary value to resources**

The next step in determining costs is to place a monetary value on each of the resources utilised. Monetary value is the value in currency that the market places on a product or service. The resource used were measured in physical or natural units (Elliott & Payne, 2005); (Slothuus, 2000). These natural units were then converted to the monetary equivalent. For HVTP study, monetary values were placed on variable and fixed components. The variable costs were defined as costs of direct labour such as medical, technical, driver and administration; fixed components were costs related to equipment and supply of consumables. For labour, time spent was calculated and converted to the monetary equivalent based on 2014-2015 pay rates for specific cadre. For each individual procedure, equipment and consumable supplies were translated into costs based on the 2014-2015 prices.

#### **Labour**

To estimate the direct labour cost per patient, the resource use data collection was implemented where everyone involved in the process accounted for time, equipment and consumables used at the stage in which they were involved. Specific criteria were applied including identifying the type of worker and the amount of time spent in an activity by that specific worker, the wage rate for that class of worker, or the cost for that type of worker.

The wage of each worker was obtained from the published 2014/2015 pay rates for the specific cadre of staff. The time information was obtained from the participating staff. Once the time spent on an activity was determined, a cost was assigned to that time on basis of the contractual hourly rate for the specific staff. Time was converted into money per respective pay scales. The labour related activities were distributed among three categories of staff members (Table 30).

**Table 30 Labour related activities in the process of carrying HVT by different levels of staff**

Staff cadre	Activities in time
Medical	Vetting referral + interviewing patient + reporting on the HVTP data
Technical	Travel between patient home and hospital + time spent in patients' homes + patient contact + review of the recorded data
Admin	Processing the referral and inputting demographic to the computer+ arranging appointments for the patient + processing the report and sending to the referring clinician

### **Transport**

The transport used for this study was part of a contracted service. The neurophysiology department at King's has a contract with a hospital transport company to provide a vehicle and dedicated driver. As the transport arrangement was on a 'wait and return' basis, the cost was calculated based on the actual journey and waiting times. The total travel and waiting times were converted to money based on the contractual figures for 2014/2015.

### **Capital equipment and auxiliary items**

Fixed assets can be defined as assets of reasonably high value offering economic benefit for the healthcare provider for more than one financial year (Lucey, 2002). Fixed assets

including equipment have an economically useful life, which, by definition, is longer than one year. This equipment is subject to wear and tear and, therefore, attracts depreciation, which should be included in the average unit costs calculation. There are different ways to calculate the cost per year of medical equipment. These include the depreciation method, equivalent annual cost method and rental value method. The department at King's uses both leased and purchased equipment.

The recording system used in the study was assembled from those that had been purchased for the home video telemetry service. The video EEG kit consisted of the amplifiers, camera, laptop, trolley and relevant cables. The costing of this HVTP equipment was obtained in collaboration with an in-house equipment development specialist in the unit who works in conjunction with specific equipment manufacturer representatives.

To allocate a fair share of equipment to a particular service, i.e., the value of the fixed asset, consideration should be made as to the working life of the particular asset, and either the acquisition costs or the replacement costs of the assets (Shepard, Hodgkin, & Anthony, 2000). The working life of equipment can vary significantly. The working life of HVTP equipment is estimated to be generally for seven years operating at full capacity. One airflow set and two respiratory bands were also required for the HVTP procedure.

### **Consumables and disposable items**

Table 31 gives the breakdown of usage of consumables during the HVTP study. Although these consumables are the same as those used in the hospital laboratory setting, at present, King's does not have the details of usage of consumables per patient. The pricing is based on the price lists available from King's purchasing department for the 2014/2015.

**Table 31 Consumables usage in performing HVTP**

Item	Quantity	Supplier	Unit price	Cost per patient
Short electrodes	A set of 25 regular 1 m electrodes was used for each patient. So total cost per patient is the unit price for the set	Unimed electrodes were used.	A set of 25 costs £11.40	Each patient <b>£11.40</b>
Long electrodes	Single use 10 x 1.5 m long electrodes were used for each patient	Unimed single use electrodes were used	The cost was £13.90 for a set of 25 electrodes.	This translates to <b>£5.56</b> per patient
Adhesive glue	Each patient required one and a half tubes	SLE collodion was used	A container with 20 tubes of 6.5 ml cost £70. Each tube cost £3.50	Each patient cost <b>£5.25</b>
Acetone	Each patient 100 ml		Each bottle= 50 ml costs 1.54.	Hence <b>£3.08</b> per patient
Bandage (K band) roll	Each patient requires one roll of K bandage		Package of 20 cost £15.79.	Therefore, each cost <b>£0.79</b>
Electrode paste	This was	Weaver Ten20	Pack of 3	The cost per

	available in a container of 228 gm. The contents were measured at the beginning and the end the study	electrode paste from Unimed was used	containers cost £27.50. A container was used for 17 patients.	container was £9.17 and, hence, each patient's calculated cost was <b>£0.54</b>
Adhesive tape	Rolls of 2.5 cm by 10 m were used.	Hypafix adhesive was used throughout the study	Each roll served 5 patients. A roll of Hypafix adhesive of 2.5 cm by 10 m cost £2.03.	Thus, each patient is estimated to have cost <b>£0.41</b>
Skin prep paste	This was available in tubes of 114 gm	Weaver Nuprep was used.	A tube of 114 gm (120ml) was used to serve 20 patients. Pack of 3 tubes=£20.00	The cost per patient was <b>£0.34</b>
Olive oil	Each bottle= 378 ml. Each patient = 20 ml		Cost per bottle= £4.09	Cost per patient= <b>£0.22</b>
Head measuring tape		Disposable measuring tape		Each patient cost <b>£0.06</b>
Q-tips	Each patient requires 2 Q-tip sticks	Farla medical	A pack of 50 costs £1.10	Cost per patient = <b>£0.04</b>

Skin marking pencil	A single chinograph marker was used throughout the study.		Usage as measured by length was divided by the number of patients and cost per patient calculated.  Length was measured at the beginning of the study and at end of the study  Each pencil serves 50 patients.	It was not possible to account for loss associated with breakages during sharpening or indeed during use.  Pack of 12 cost £20.  Therefore, each patient cost <b>£0.03</b>
Cotton wool	Each patient=4 balls		Each pack of 200 balls=£1.65	Cost for each patient= <b>£0.03</b>

### 6.2.5 Summing up the total cost for the cost object

After all cost items were identified for each patient, the total cost per patient was obtained by summing up the costs. These were added together to provide the total cost of HVTP for all patients. An average was then calculated for all the patients to provide the cost of HVTP per patient in this study. The total costing included costs associated with the main HVTP recording kit and auxiliary components, consumables, transport and labour related costs. This estimation provided a bird's eye view of the cost elements involved in the HVTP

process. This would form a base tariff that could be used to compare with King's College Hospital laboratory video telemetry polysomnography (LVTP) tariff to determine the economic viability of HVTP as a clinical service in follow up studies.

### **6.3 Results**

Costing analysis from the perspective of the provider of the health care services was performed using activity process costing and participation methods for all transactions involved in the HVTP studies process. The production process of a HVTP procedure in this study consisted of activities that could be described in a time sequence. A total of 17 steps or activities were identified. Analysis of these activities provided information that was useful in informing the feasibility of HVTP.

#### **6.3.1 Demographics**

The HVTP process was performed on 21 patients within a period of 15 months between September 2014 and December 2015. The geographical area covered ranged between 1.1 and 38.8 miles with an average of 13.5 miles. Three round-trip journeys were undertaken for each patient.

#### **6.3.2 Labour**

The medical related labour costs, consisting of different activities undertaken by the clinicians, are summarised in Table 32. Four consultants were involved in this process. Based on the information provided by the consultants, and by observing some of the activities, it took an average of approximately 6.75 minutes to vet referrals, 25 minutes to interview the patient while taking the clinical history and 93.75 minutes to review the HVTP data and prepare the clinical report. Time spent for all activities per patient by different consultants varied between 90 to 153 minutes. Each patient, on average, took 125.5 minutes of consultant time. The consultant work plan is in the form of Programmed Activities(PAs), which are blocks of four hours spread over five days working between 07.00 to 19.00 hours, Monday to Friday. This means a consultant is contracted for 10 PAs of four hours per week, which is equivalent to 40 hours a week. The salary scale for consultants range from £75,249 to £101,451 (2014/2015 pay scale). The midpoint of this pay range is £88,350. The hourly

rate for this pay would be £42.75. Thus, a time of 125.5 minutes would be £89.40 per patient.

**Table 32 Average medical related labour costs based on four consultants' activities**

Transaction/consultant	Consultant 1	Consultant 2	Consultant 3	Consultant 4	Total	Average
Referral vetting (Min)	4	3	5	15	27	6.75
History/ interview (Min)	20	30	20	30	100	25
Reporting (Min)	90	120	120	45	375	93.75
Total	114	153	145	90	502	125.5

The clinical physiologist's time was split between travel time, patient contact time or the time spent in the patient's home, and reviewing the recorded data and analysis time. Travel time was 270.5 minutes (Table 33).

**Table 33 Physiologist's travel time between hospital and patients' homes**

Return journey travel time in minutes consisting of 6 legs spread over 3 days								
	Miles	Leg 1	Leg 2	Leg 3	Leg 4	Leg 5	Leg 6	Total
Minimum distance	1.1	12	13	12	10	10	10	67
Maximum distance	38.8	113	74	88	87	148	83	593
Total	283.4	930	928	930	916	975	1006	5686
Ave	13.5	44.3	44.2	44.3	43.6	46.2	47.9	270.5

The patient contact time was spread over the three days of home visits and represented the time spent by the clinical physiologist in the patient's home. Table 34 summarises the times spent in the patients' homes. The average time per visit ranged from 31.1 minutes to 127.8 minutes. The total contact time per patient was 210.8 minutes

**Table 34 Physiologist's time in patients' homes**

Patient contact time: time spent at patients' home in minutes				
	Day 1	Day 2	Day 3	Total
Minimum time in minutes	100	20	39	159
Maximum time in minutes	176	50	67	293
Total for 22 patients	2684	654	1089	4427
Average per patient	127.8	31.1	51.9	210.8

Review and analysis time included fast scanning to look for background abnormalities in the EEG using extended montage for two nights, sleep staging and event quantification for one night including pruning relevant portions of the recording, and filling out the associated paperwork. Table 35 summarises the review and analysis times. On average, review with analysis time was 206.35 minutes per patient.

**Table 35 Physiologist's data review time**

Category	No of patients	Average time (min)	
Scan/raw data review	21	63	All the patients' data required fast scanning review for both days to look for background EEG abnormalities
Sleep scoring	19	56.8	Those requiring sleep staging for one night to generate a hypnogram
Event quantification	11	86.55	Those requiring sleep staging and quantification of events such as PLMs for one night
		206.35	

The clinical physiologist spent a total of 687.65 minutes on the project (270.5 minutes for travel, 210.8 minutes in the patient's home and 206.35 minutes for data analysis). This is equivalent to 11.46 hours per patient. The pay scale for those deemed competent for home studies ranges between Agenda for Change (AfC) pay scale Band 7 up to Band 8B. The top end of Band 7 scale for 2014/2015 AfC pay scale, including London weighting, was £24.08 per hour. This translated to an average of £275.96 per patient.

The administrative costs were split into several activities including referral processing and appointment, telephone interview to assess the patient's environmental suitability for a home visit and report processing including dispatch time. They were computed as per the respective administrative staff involved, using the pay scales for 2014/2015. Table 36 shows

the administrative labour related costs. The total cost per patient for these administrative transactions amounted to £4.40.

**Table 36 Administrative related costs for non-clinical staff involved in HVTP process**

	Avg. time in min	AfC grade pay point	AfC 2014/2015	£
Referral process and appointment	5	C (mid-point)	17,972	0.76
Telephone assessment	5	8B (mid-point)	49,968	2.1
Report process & dispatch	10	C (mid-point)	17,972	1.54
				4.40

### 6.3.3 Transport

Transport formed a sizable component of costs for the HVTP procedure. As the transport arrangement was on a 'wait and return' basis, the cost was split between driving time and waiting time. The total amount of time associated with travel for the driver was similar to the clinical physiologist's travel time and patient contact time.

Travel time=270.5 minutes (same as total travel time for clinical physiologist)

Waiting time=210.8 minutes (same as total patient contact time for clinical physiologist)

Total=481.3 minutes, which is equivalent to 8 hours

The transport was contracted at a weekly rate of £900 regardless of the usage. The week consisted of 40 hours. The hourly rate was, therefore, £900 divided by 40 hours which gives

£22.5. Based on an hourly rate of £22.5, with each patient accounting for eight hours on average, the cost per patient was £180.

### **6.3.4 The HVTP recording system**

The main recording system consisted of the main HVTP recording machine and the respiratory related accessories. Table 37 summarises the cost of these components per patient. The manufacturer estimates the working life of HVTP recording machines to be seven years. The full working capacity in the unit at King's college Hospital records three patients a week, including weekends. The recording system is expected to be operational for 50 weeks per year to allow for downtime, servicing and preventive maintenance. A standard video-EEG system, which includes PSG capability, is estimated to cost about £35,000. The maintenance is estimated to be 10% of the cost per year. With a capital cost of £35,000, a 10% maintenance cost would be £3,500. With an estimated working life of seven years, working for 50 weeks per year and attending three patients per week, a total of 150 patients can be attended per year. This would translate to £36.67 per patient.

The accessories of the HVTP kit consisted mainly of the respiratory related items. The respiratory monitoring kit included reusable airflows and respiratory belts. One airflow thermistor was required for the study; this cost £152 and was expected to last for one year and, hence, serve 150 patients. Two piezo respiratory effort kits consisting of the Velcro strap, piezo sensor and connector were also required. The respiratory belts, costing £147 x 2 = £294, were expected to last for one year and, hence, serve 150 patients. Each patient requires two respiratory belts. The total cost of one airflow and two respiratory belts was £446. This, divided by 150 patients per year, translates to £2.97 per patient.

**Table 37 HVTP recording system costs per patient**

Item	Quantity	Cost	Maintenance	Working life in years	Capacity	Cost/patient
HVTP system	1	35,000	3,500	7	1050	£36.67
Airflow	1	152	Nil	1	150	£1.01
Respiratory Belts	2	294	Nil	1	150	£1.96
Total						£39.64

### 6.3.5 Consumables

Table 38 shows the average cost per patient for consumables, which amounted to £28.75 per patient.

**Table 38 Cost of consumable items**

	Item	Quantity/pt	Unit price in £	Cost in £/pt
1	Short electrodes	25 elect	Pkt 25 x 1 m=11.40	11.4
2	Long electrodes	10 elect	Pkt 25 x 1.5 m=13.90	5.56
3	Collodion glue	1.5 tubes	A 20 tube packs=70	5.25
4	Acetone	100 ml	50 ml bottle=1.54	3.08
5	K-bandage	1	Pack of 20=15.79	0.79
6	Electrode paste (ten20)	13.4 gm	3 x 228 gm=27.50	0.54
7	Adhesive tape (Hypafix)	5pt/roll	2.5 cm x 10 m=2.03.	0.41
8	Nu-Prep	5.7 gm	3 x 114 gm=20.00	0.34
9	Olive oil	20 ml	378 ml bottle=4.09	0.22
10	Disposable measuring tape	1	Pack of 100=6.00	0.06
11	Q-tips	2	Pack of 50=1.10	0.04
12	Chinograph pencil	1/50 pts	Pack of 12=£20	0.03
13	Cotton wool balls	4 balls	Pack of 200=1.65	0.03
Total				27.75

### **6.3.6 Total cost for HVTP**

Table 39 shows the summary breakdown of labour related costs, which accounted for the largest portion of HVTP costs.

**Table 39 Labour related cost breakdown**

Main cost (cost driver)	Amount in £	% of total HVTP cost
Physiologist	275.96	44.7
Medical	89.40	14.5
Admin	4.40	0.7
Total	369.76	59.9

Table 40 shows a summary breakdown of the costs for the entire HVTP process. It cost an average of £617.15.

**Table 40 Summary of total cost of performing HVTP**

Main cost (cost driver)	Amount in £	Percentage
Labour including travel	369.76	59.9
Transport (contracted)	180.00	29.2
Capital equipment	39.64	6.4
Consumables	27.75	4.5
Total	617.15	100.00

## 6.4 Discussions

The increasing financial pressures on health care mean that clinical services must become more cost efficient in their use of resources, and sleep studies are no exception to this. Some health services are complex to cost, partly because of the multifactorial resources that are needed to meet the requirements of a specified cost object, but also because there are logistical difficulties in finding a single costing method that can fulfil all the requirements for a cost object.

Not only are HVTP recordings complicated by the various components required in the process of recording, but also by the fact that sleep disorders are heterogeneous, requiring different recordings or emphasising specific recorded parameters. To address this

complexity, consideration of resources in terms of skill and equipment is necessary. Consequently, the costs of HVTP are both high and inevitably variable. It is, therefore, important that an accurate costing methodology is developed that allows the costs incurred in delivering this type of service to be analysed in detail, and to allow reasonable decisions to be made regarding appropriate resource allocation. The importance of such an exercise is that actual resource consumption is a more reliable method of determining the cost of providing services than using various indirect methods to estimate them (Finkler, 1982).

This exercise was particularly relevant to HVTP since this type of service is experimental and requires both clarity of costs and how these costs relate to hospital based tariffs. The process based costing (PBC) approach, which was used in this study, has been proposed as a simple and inexpensive costing model that is based on participant interviews (Lee et al., 2003); this is in contrast with the direct observation method where the researcher has to observe and document activities as they are being performed by other staff. The PBC method allowed the flexibility for the researcher to interview or look through the documentations of the staff participating in the HVTP process. Although the participants' interviews method is less accurate compared to direct observation, it still allowed a more precise and detailed allocation of costs to each transaction procedure by interrogating entries recorded or by seeking clarity from participating staff concerning each transaction a patient underwent while completing an HVTP process.

#### **6.4.1 Main findings**

Twenty-one HVTP procedures for PSG were carried out within a period of 15 months between September 2014 and December 2015. The distance covered from the hospital to patients' homes ranged from 1.1 to 38.8 miles, with an average of 13.5 miles. The HVTP procedure was carried out for two nights. Seventeen transaction costs were identified, and their sum equalled the total cost of an HVTP procedure.

The average cost of HVTP per patient was £617.15, compared to the standard hospital tariff of £998.49 for a similar procedure. The standard hospital tariff is amount the hospital has

allocated for this procedure and is unclear how this figure was arrived at. Labour accounted for 59.9% of the total cost and transport accounted for 29.2%. The clinical physiologist's labour related costs including travel time accounted for 44.7% of the total cost per patient, medical related labour costs were 14.5% of the total cost per patient while administration related cost was 0.7 % of the total average cost.

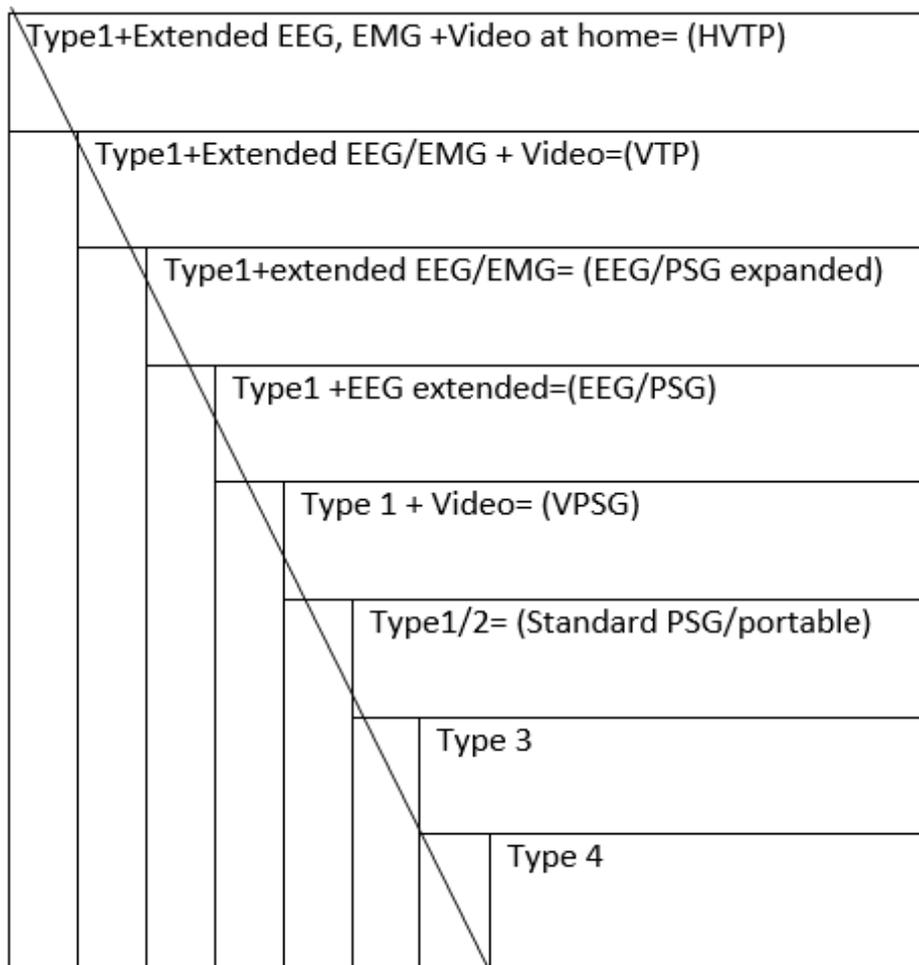
#### **6.4.2 Cost feasibility of HVTP**

Full-PSG, which is an attended recording of neurophysiological and cardiorespiratory parameters, is accepted as the gold standard for sleep and sleep disorders assessment (Kushida et al., 2005). However, this gold standard raises several issues including its high cost. Portable devices have been introduced to circumvent some of the problems associated with LPSG. A major attraction of using portable devices for home recording is that they are seen to require less technical expertise, are less labour intensive, less time consuming, and are easier for patients to access (Chesson et al., 2003). These are important areas that need to be adequately addressed before the benefit of portable devices can fully be realised.

The greatest attraction of Type 2 portable recordings is eliminating the need for hospitalisation and the reducing related costs, potentially resulting in important cost savings; however, few data related to formal cost analysis are available (M. Bruyneel & Ninane, 2014). Some studies suggest they may be more cost effective than attended PSG (Angela J. Campbell & Alister M. Neill, 2011), assuming that no overnight staff is required, but they are often not practical because technologists must travel to the patient's home to set up the leads and then retrieve the monitor the next day. Using a system where patients were set up in the hospital and then took the recording system home, Portier et al. (2000) found that Type 2 home sleep studies reduced the cost of hospital sleep studies by 50%; however, with a failure rate of 20%, it would cause increases in costs due to repeat tests. A more recent study by Campbell and Neill (2011), where set up was done in patients' homes, estimated that Home Polysomnography (H-PSG) costs compared to Laboratory Polysomnography (L-PSG) accrued a saving of 25%, when adjusted for failed recordings. Bruyneel et al. (2011) reported that payments were substantially higher in the laboratory if hospitalisation costs were included (1057 EUR vs 268 EUR). Lack of studies adequately

addressing cost as part of their evaluation in this area makes it difficult to draw any conclusions about possible savings with these types of portable home monitoring.

A second difficulty in drawing conclusions on cost implications from these previous portable or home studies relates to the level of complexity of the different types of sleep studies. Sleep studies range from single channel monitoring to highly complex multi-channel, multi-parametric studies with video facilities (Figure 22). This rising level of complexity builds from the AASM'S Types 1 to 4, which mainly range from respiratory sleep disorders monitoring to more complex studies suited to other sleep disorders such as parasomnia (Verbaan, van Rooden, van Hilten, & Rijsman, 2010)).



## **Figure 22 Rising level of complexity of sleep studies with expanded Type 1/Type 2 parameters**

Note: Type 1 and 2 are similar in the number and type of signals recorded except that Type 1 is a laboratory-based system and Type 2 is portable system.

There are hardly any studies that have addressed cost in home video EEG-PSG with extended montages suitable for the complex differentiation of nocturnal frontal lobe epilepsy with parasomnia and other sleep related movement disorders.

A third difficulty in drawing conclusions from the previous studies, with regard to cost, relates to the disease conditions evaluated in the home environment. Most of the reported studies have assessed patients with respiratory related sleep disorders. The heterogeneity of sleep disorders necessitates different requirements in terms of sleep features that need to be monitored. The cost implication will depend very much on the parameters measured and the duration of monitoring that may be required to adequately address the specific clinical problem. The HVTP model presented in the current study allows for extended montage with added EEG and EMG channels in conjunction with synchronised video recording. The study endeavoured to identify cost elements in carrying out HVTP and identifies various cost drivers that require careful consideration prior to adopting such procedure as standard clinical service. The results of the present study show that it was feasible to carry out a complex HVTP at a cost that was far less than the tariff allocated to an equivalent hospital setting (£636.55 compared to £998.49).

### **6.4.3 Main cost drivers**

In the present study, labour and travel related costs ranked very high in the cost implications for HVTP, with the clinical physiologist's costs accounting for about 417.2 minutes per patient in labour time, excluding travel time. This was mainly due to the fact that the clinical physiologist performing the procedure spent a considerable amount of time preparing the patient for the study with a full set of scalp electrodes, extra surface EMG channels and cardiorespiratory parameters. They also spent time retrieving and reviewing the data recorded over the course of the two nights' study. While this may be an expensive

undertaking from the perspective of the health care provider, it needs to be seen in the context of the other comparable alternatives. The Department of Health's guidelines allow up to 480 minutes for similar kinds of work including reporting on a patient admitted to a telemetry unit for two nights (DoH, 2007). The standard operating procedures for sleep medicine centres in the 2012 European guidelines allow 180 minutes for standard one-night PSG, which does not include the extra EMG and EEG channels in addition to the need to have staff to observe the patient for eight hours throughout the night (Fischer et al., 2012). The most significant and practical finding from the present study is in relation to the local practice at King's College Hospital. The telemetry unit at King's provides for up to 145 minutes for setting up, 60 minutes for straightforward fast review or scanning for day one (120 minutes for two-day recording), 150 minutes for review and staging, and 60 minutes for maintenance of recording, making a total of 415 minutes. An average of 417.2 minutes was used for similar kinds of activities for the present HVTP study. This compares favourably with the hospital allocated time of 415 minutes, suggesting that HVTP does not add significant extra time for similar activities.

Patients often cite transportation issues as barriers to healthcare access (Syed, Gerber, & Sharp, 2013). For some patients, travel to receive healthcare can present difficulties such as lengthy or complex journeys, cost implications and even sometimes difficulty in accessing public transport. A possible solution for such situations would be to go to the patient to carry out the whole procedure in the patients' home. This of, course, transfers the travel cost burden from the patient to the service provider. Travel time is highly variable and is influenced by various travel conditions experienced on the road and the distance travelled, all of which add cost to the procedure.

In sleep studies, portable devices have been used where the patient attends the hospital for set up, takes the device home and brings it back the following day (Portier et al., 2000). This arrangement, of course, does not favour the patient in terms of travel costs. The same study by Portier et al. (2000) reported that patients living more than 40 kilometres from the hospital frequently preferred to be studied in the laboratory, rather than making two trips to the hospital. Fry et al. (1998) also experienced problems in performing H-PSG in some

patients because of transportation difficulties. According to Bruyneel and Ninane (2014), the costs of home sleep studies are largely related to the necessity for specialised technical staff to visit patients' homes. Despite this observation, the present study adopted the method of travelling to patients' homes and performing the entire procedure there. The results of this study show that contracted transport on a wait and return basis, of which 270.5 minutes were spent on travel and 210.8 minutes on waiting, at a rate of £22.50 per hour, translates to £180.00, accounting for 29.1% of total cost; in addition, the physiologist's travel time of 270.8 minutes, at a rate of £24.08 per hour, translates to £108.60, which accounts for 17.6% of the total cost. On average, travel related costs accounted for 46.7% of the total cost. Travel related cost is, therefore, a significant variable to consider in planning and implementing comprehensive HVTP.

#### **6.4.4 Limitations**

##### **6.4.4.1 Methodological difficulties**

In health economic evaluations, direct costs are the costs of all goods, services and other resources that are consumed in the provision of a health intervention and can be medical or non-medical. Therefore, if the resource consumption of any activities can be measured more accurately, a more accurate cost estimate can be calculated. The micro costing approach is particularly useful for estimating the costs of new interventions or treatments when there is no established estimate for their aggregate costs.

The costs of HVTP can be classified into two categories. First, there are direct health care costs referred to as the physical health resources required to produce an HVTP recording and report. Secondly, there are non-health care costs that are outside the health care sector such as time costs associated with patients' loss of income due to being home for the study and costs associated with childcare for those who need someone to take their children to school. The present study only reported the direct health care costs.

A major component of identifying activities involved in the HVTP process was recording the time spent at each stage; this included whoever was involved, whatever resources were

used and the amount of those resources. One of the critical issues in recording time is determining the detail of relevant activities and scope of a process. A clear definition of activities and the criteria for defining the scope of each activity would increase the accuracy of the recorded times. Time and motion activity based costing using trained observer based data collection, has been reported to provide the most accurate account (Laurila et al., 2000; Nisenbaum et al., 2000; Van Zanten et al., 2003). However, this method is expensive and impractical in the present study. A more practical and cheaper method, which was used in this study, was to use a participant method of data collection. The problem with participant methods is that biases in the data collection can occur when individuals record time differently, use inappropriate assumptions about the beginning and end points of activities, carry out activities in a different order, or use estimates instead of actual activity times. Anticipation of these potential biases and the intensive training of all the staff involved in data collection would have improved the quality and reliability of the study, an aspect that was not fully fulfilled in the present HVTP study.

Additionally, indirect costs were not fully addressed in this study. In a study in Ontario, Canadian hospitals showed that the portion of indirect costs in the cost price of services accounted for 40-45% of total costs (Doyle, 2006). In another study in Iran, the indirect costs accounted for 27.28% of the total costs (Nouroozi, Vadiee, & Ravangard, 2013). Owing to variations in indirect costs, the implication and significance of all indirect costs in the present HVTP study is an area that requires addressing.

#### **6.4.4.2 Measurement difficulties**

Distortions in cost data can also occur due to the variations of details of cost information, inaccurate cost information, or the use of a proxy for costs; for instance, individuals of different grades can perform a certain activity. Sometimes there may be a wide gap between these grades. When a member of staff at the top of the AfC pay grade Band 8B performs the same activity as another member of staff at the bottom of pay grade Band 7, the difference in the cost object could be substantial. In the present study, for example, the average contact time for day one setting up was 127.8 minutes. The top end pay for Band 8B was £56,504 and the bottom end of Band 7 was £30,764; both were contracted for 37.5

hours per week using the 2014/2015 AfC pay rate. This means that for setting up on day one, the difference in costing for this specific activity was £28.1 (£61.7-£33.6). Although it can be argued that the same disparity would apply in the hospital setting, the present study showed that travel costs contribute significantly to the cost of HVTP. The differences occasioned by travel would not apply in the hospital setting. With a large percentage of direct costs being spent on labour and travel related activities, there is clearly a need to carefully consider the most economical strategy for home studies.

#### **6.4.4.3 Problems of estimating time data**

Another methodological problem was obtaining accurate data. During the study, some clinicians involved were asked to estimate the average amount of time spent on referral vetting, taking histories and reporting the HVTP the data. The same was applied to the administrative staff that processed the referral, made telephone calls and processed the final report. As these are largely participant reports, there may be some unintended inaccuracies.

#### **6.4.5 Implications and significance**

While the HVTP may be viewed as an expensive procedure, considerable savings can be made when compared to hospital tariffs. For example, the hospital tariff for PSG is £998.49. The results of the present study showed an average cost of £617.15. This makes a saving of £381.24, which is about 38.2%. Home sleep studies have been offered as a less expensive screening tool for sleep disordered breathing in previous studies. Pelletier-Fleury et al. (2001) compared unattended PSG against telemonitoring and concluded that, unless some specific geographical situations generate significant transport costs, the implementation of a strategy based on unattended H-PSG is cost-saving compared to a telemonitoring strategy. In the present study, it has been shown that complex HVTP can be performed with fewer costs compared to a similar set up in the hospital environment.

The ability to monitor the patient's sleep in the comfort of their own home has the potential to increase efficiency of the healthcare system with an added benefit of potentially improving their quality of life. Furthermore, evaluation of patients in their home

environment may yield a better understanding of sleep disorders for both research and clinical studies.

Telemedicine is developing, and studies performed with remotely attended H-PSG systems, in order to enhance the quality of the recordings, are encouraging. The ideal future would be to simplify the technical aspects of H-PSG systems, allowing the patient to set up the recording device at home and to couple it with remote monitoring in order to obtain optimum quality (Bruyneel et al., 2013).

It will be necessary to conduct detailed comparative cost analysis for both hospital and home studies, from both provider and societal perspectives. This is an important consideration because cost containment is an issue directed at the health care provider, who is being asked to increase production and to do so at a lower cost. With regards to the home visits, several measures might be helpful. First, there is the possibility that the number of home visits can be cut down during recording if there is evidence that this does not compromise signal quality. Second, the simplification of equipment and recording strategies can be explored to allow for shorter set up times. Third, it is worth considering staffs' skills mix to allow for the most economical arrangement for those who carry out home visits. Fourth, a considerable amount of cost was also attributed to travel. A wait and return arrangement meant that the driver spent as much time in travel and waiting as the attending practitioner attending. An arrangement that removes a driver out of the equation might help in cutting down the cost.

## **Chapter 7: Overall discussions**

This chapter contains an overview of the study methodology, the study population, a discussion of the main findings, the study limitations and some suggestions for future research.

Comprehensive LPSG is currently considered the gold standard in the diagnosis of sleep disorders. This procedure involves the use of multiple channels to record a wide range of physiological information, including neurophysiological and cardiorespiratory channels. Advantages of this procedure include the ability to diagnose other non-respiratory related sleep disorders. Traditionally, these comprehensive sleep studies are carried out in the laboratory in a monitored setting to ensure the overall quality of the recording. The cost of monitoring a person overnight, the scarcity of beds available, and the uncertainty of how representative the results are of a normal night's sleep are some of the limitations of the present gold standard.

This pressure on bed availability, the financial constraints and need for patient centred service compels NHS service providers to explore ways of becoming more efficient in their service delivery. A service that maximises the outcomes produced by the activities the NHS carries out, while minimising their costs. The drivers of change are multiple and overlapping. They include a combination of technological, clinical, cultural, policy and economic changes that have worked together. There is evidence, for example, to support that the notion that involving patients has contributed to changes in the provision of services across a range of different settings (Crawford et al., 2002). With regard to sleep studies, a move to home sleep studies is likely to be advantageous. However, while the potential to carry out a comprehensive sleep study in a patient's home is there, the complexity associated with recording heterogeneous multiple physiological and non-physiological parameters in a non-dedicated environment makes such a study a challenging undertaking.

In the spirit of making our services better, the present multimodal feasibility research project was part of Clinical Neurophysiology patient care delivery Service improvement initiative. The study sought to explore the feasibility of HVTP as a method of sleep study

for assessing patients suspected of having a parasomnia. Parasomnias are a group of sleep disorders characterised by aberrant electro-clinical features occurring during the sleep period. This project defined HVTP as a complex multiparametric sleep study with a total of 30 channels recording cardiorespiratory and neurophysiological signals, as well as synchronised audiovisual signals recorded at the patients' homes for two nights. The determination of feasibility in the present study was anchored upon three fundamental pillars: quality of the data recorded parameters, acceptability of the procedure by the patients, and the cost implications of carrying out the procedure in the patients' homes.

### **7.1. The overall findings**

The use of digital PSG recordings for clinical purposes in patients with sleep disorders is increasing as technology has become more portable and efficient, and data storage becomes less cumbersome. There were two specific challenges associated with this study. First, there was the challenge associated with finding the best method of addressing the different aspects of determining the feasibility of HVTP; second, there was the challenge associated with both the recording of complex multi-parametric data sets simultaneously in an unsupervised environment, and determining the data quality of the signals. In order to address this first challenge, a mixed methodology with three strands was adopted to validate findings using both quantitative and qualitative data sources; in addition, qualitative and quantitative outcomes were used to augment the meaning of the study's results. To address the second challenge on recording and determining quality, recording equipment was adapted to the home environment and a criteria for the readability of each data set was developed. Although data quality might seem to be the most important of the three, any of the other two could render HVTP impractical. In other words, good quality data obtained in a manner unacceptable to the patient is not viable for clinical practice. Likewise, if the process of obtaining such data is too expensive, the providers of the clinical service might find it untenable.

The results of this study showed that using an objective numerical grading criteria, data quality was readable without difficulty in 97.6% of cases with a failure rate of 2.4%. Compared to the cost of similar types of procedures in a hospital setting, the costs of

HVTP were 38.2% lower. The results of the feasibility study also showed that the patients accepted the procedure with burden of parasomnia, environmental factors and financial considerations emerging as main drivers for acceptance. Although some patients raised concerns particularly in regard to the technology related issues, overall there was a general indication from all patients that, regardless of the inconvenience it might have caused, they still would have preferred to have the procedure to be carried out at home.

## **7.2 Limitations of the present study**

The difficulties involved in carrying out sleep studies unsupervised and in a non-dedicated environment such as the home include the fact that data can be lost for various reasons including equipment failure, sensors falling off, or poor quality signals. In a study by Ayappa et al. (2008), as much as 14% of the sleep time data was lost. A crossover study comparing unattended H-PSG to nurse-attended PSG in a local hospital found that data was inadequate for interpretation in 23.4% of cases compared to 11.2% of attended studies (Gagnadoux et al., 2002). Portier et al. (2000) reported a failure rate of 20%; Kapur et al. (2000) reported a failure rate of 9.4% and BaHammam (2005) reported a failure rate of 3%. In the present study, one out of the forty-two nights failed due to a lack of disc space, representing 2.4%. The differences in signal quality among different studies may be attributed to the techniques used and the guidance given to the patients. There were more failures in studies where connections were carried out in the laboratory with patients taking the recording system home: 23.4% for Gagnadoux et al. (2002), 20% for Portier et al. (2000), and 14% for Ayappa et al. (2008). This is in comparison to studies where connections were carried out at the patients' home by a qualified practitioner; 9.4% for Kapur et al. (2000), 9% for Marcus et al. (2014), 3% for BaHammam (2005), and 2.4% in the present home study. The overall low signal failure can be attributed to the technique used for hook-up and the equipment used; this is an aspect that can be addressed technically, as reflected in the present study.

Of particular note in the present study is the absence of oximetry monitoring due to technical problems. Oximetry is a major component of assessing the quality of sleep studies. for a number of reasons. Firstly, conditions that provoke repeated cortical

arousals, or promote sleep inertia lead to NREM parasomnias by impairing normal arousal mechanisms (Howell, 2012). In a study by Ratti and others, a respiratory event was recognized to trigger Parasomnia behaviours (Ratti et al., 2015). Secondly, clinical features between parasomnia and sleep disordered breathing overlap (Pevernagie, Boon, Mariman, Verhaeghen, & Pauwels, 2001). For instance, catathrenia which is associated with end-inspiratory apnoea and expiratory groaning has only recently been described as a new distinct type of parasomnia (Prihodova, Sonka, Kemlink, Volna, & Nevsimalova, 2009). Thirdly, patients with obstructive sleep apnoea have a high frequency of parasomnias (Viola-Saltzman, Kumar, & Undevia, 2009) and night terrors, can be triggered by sleep apnoea (Pressman et al., 1995). Fourthly, it has been observed successful treatment of sleep disordered breathing led to the disappearance of parasomnias (Cao & Guilleminault, 2010; Guilleminault, Palombini, Pelayo, & Chervin, 2003). There is clearly a link between disordered breathing and parasomnias and the inability to include oximetry in this study was a limitation.

However, taken in the context of the clinical problem, it can be argued that the relevance of oximetry in this study was limited and mostly not required because the present study investigated parasomnias and oxygen saturation was not relevant for diagnosis (Tinuper, Bisulli, & Provini, 2012). Furthermore, where parasomnia behaviour was complicated by respiratory events such as respiratory effort related arousals, inclusion of airflow in conjunction with EEG made scoring of the events possible. Notwithstanding these arguments, in hindsight, readily available stand-alone oximeter, though not synchronised into the main recording system could have been used. Since the absence of oximetry in this study was technical as the equipment set-up was a modification of the conventional EEG telemetry system in our unit, there is no reason why future studies should not have oximetry incorporated into the recording system.

Another difficulty in sleep studies concerns the present gold standard. Most of the reported home sleep studies involve patients with respiratory related sleep disorders and the present gold standard is heavily biased towards such disorders (Pevernagie et al., 2006). The present gold standard is not directly applicable to all clinical scenarios in sleep

medicine. Objective sleep measurement methods can be divided as follows: (i) sleep disorder-specific, (ii) PSG, (iii) generic sleep– wake patterns; there is possible overlap in the categories depending on the sleep disorder or the detailed information needed (van de Water, Holmes, & Hurley, 2011).

The method of determining the quality of sleep studies deserves special consideration. A period of three to four hours of sleep is generally accepted as the minimum duration of recording required for a study to qualify for further analysis (Gagnadoux et al., 2002; Kapur et al., 2000; Portier et al., 2000; Redline et al., 1998). While this may be appropriate when quantifying sleep or sleep related events in some sleep disorders, it is questionable whether it is appropriate for other sleep disorders such as parasomnias. Patients with parasomnias have discrete behavioural events that characterise the nature of the sleep disorders. Sometimes those discrete events include waking up and moving out of their sleeping environment. If such events occurred in the first two hours of the study, and the patient is disconnected in the process as part of the evolution of the event in question such as walking away, that study would automatically be considered a failed test using the duration criteria. This would be misleading since the capturing of a parasomnia event is a successful test. Further, the duration criteria do not take into account the sleeping pattern of the patient. For instance, in the present study, one patient routinely slept for a very few hours and spent most of the night on the computer working; this did not mean that the procedure was inadequate.

Among the limitations of the present study is the lack of comparison with similar studies from other centres. The present study was carried out in a single centre with most work being done by a single researcher. Single-centre studies are often an essential starting point for testing interventions and they allow larger, multicentre studies to be planned appropriately. However, single-centre studies frequently lack the scientific ingredients required to support widespread changes in practice. An obvious shortcoming in the present study is the potentially limited external validity. It is not clear whether present HVTP procedures carried out in the present single clinical environment can necessarily be

generalisable to a broader population. Collaboration with other centres in the future would be advisable.

Furthermore, the sample involved in this study was small and drawn from a specific geographical area. A single researcher carried out most of the present study as part of his personal development. This, in itself, may be a limiting factor in some ways because a protagonist with highly atypical expertise and commitment performs the study. In a review article, Bellomo, Warrillow, and Reade (2009) argue that if delivery of a complex intervention relies on such dedication, it may be impossible to implement elsewhere. The advantages of a single centre study are that they are usually small-scale studies and cheaper to conduct than multicentre studies. They provide the flexibility of approach necessary for researchers to develop new interventions and can provide an important source for new ideas. The present study was a feasibility study to find out if HVTP could be done successfully and to identify important elements involved in such a process to allow for a larger study.

### **7.3 Conclusions**

Home sleep recordings have been carried out for many years to assess sleep disorders. However, there seems to be great variation in the manner in which these studies are carried out and the outcomes reported. In spite of considerable advances in medical technology, sleep studies have not taken full advantage of this technological advancement to improve its quality. In order for a truly universal system for monitoring sleep and diagnosing disorders to become a reality, it must be moved from the centre to the home. A meta-analysis of home verses laboratory sleep studies by Ghegan et al. (2006) in the diagnosis of obstructive sleep apnoea patients found that home sleep studies provide similar diagnostic information to laboratory polysomnography studies in the evaluation of sleep apnoea, lending some support to the idea that home environment sleep studies are a viable alternative to laboratory sleep studies. Evaluation of such models to ascertain the quality of the obtainable sleep data, along with its acceptability to patients and the cost implications, would be a first step in establishing this model as a clinical service and a potential gold standard for the comprehensive method of assessing

a wide range of sleep disorders. The sparsity of data on such a comprehensive PSG recording system, with reference to patients undergoing investigations for parasomnias in a home environment, prompts this feasibility study. The present feasibility study represents the first attempt to evaluate the quality, acceptability and cost of a comprehensive HVTP in patients suspected of parasomnia. The present study showed that HVTP is technically feasible, acceptable to patients and economically viable in patients suspected of parasomnia. Moreover, the inclusion of extra EEG and EMG channels synchronised with audio-visual recording lends this model of sleep studies as a potential gold standard for non-respiratory related sleep disorders assessment.

#### **7.4 Future studies**

Developing a consensus on the best way to standardise the procedures of home sleep studies is urgently needed. It is necessary to move beyond assessing parameters based on specific sleep disorders such as sleep disordered breathing to more inclusive procedures, or alternatively to develop a consensus on the use of procedures tailored to specific sleep disorders. The urgency recognises the fact that many non-respiratory sleep disorders such as RBD are becoming increasingly important in their association with other neurological disorders such as Parkinson's disease. The present feasibility study on suspected parasomnia patients may hopefully lead to larger future studies that can assess the diagnostic validity of HPSG and standardise it for more widespread use.

In the present study, travel cost formed a substantial contribution to the overall cost. As technology advances, better equipment can help reduce travel related costs. For instance, since the completion of data collection for this study, there is now a company that has developed a system whereby the patients can do most of the set up themselves after sensor applications are done in the hospital. Furthermore, better equipment might help reduce the number of visits from three to two and, hence, cut travel costs. It is, however, unclear how these two aspects would impact upon the quality of the recorded data. A future study might want to explore this aspect.

The present study has been conducted on a group of patients drawn from a single referral centre on a specific group of patients. Consequently, the results of these studies

may not be generalisable to other groups of sleep disorders. Future studies should include more diverse populations including patients recruited from other centres. Future studies should also address the issue of collaboration with other centres to alleviate problems associated with single centre studies.

In addition, the study design should address the comparison between unattended HVTP monitoring and attended standard based LVTP. The order in which a patient's HVTP and LVTP monitoring studies are done should also be randomly assigned to avoid a possible order effect. This would help to determine the effectiveness of HVTP and its validity for clinical utility.

## Chapter 8: Reflection

*“The story we choose for ourselves, the story we live, can sacralise or secularize our lives and our world by the way in which we choose to relate to it” (Novak, 2009, back cover page).*

### 8.1 Introduction

The changing landscape of the NHS, in conjunction with innovations in science and technology, present opportunities for new roles and functions for the healthcare science workforce. Rapid advances in science and technology are changing the way in which services can be delivered. This requires healthcare science practitioners to adapt and adopt new knowledge and skills to meet increasing demands. Health care science practitioners are expected to have the necessary expertise in applied scientific techniques within their specialisms to work in a range of healthcare settings. Indeed, most professions mandate that their members continue learning in order to maintain their license to practice (Merriam, Caffarella, & Baumgartner, 2006). The complexity of NHS care delivery requires that employees, including practitioners to engage in lifelong learning to maintain relevant professional expertise. Where workers need to adapt to fit changing roles, continuous learning is required (Heyler, 2015). As a practitioner, my professional development forms an important component of this long-life journey and embarking on a professional doctorate programme was a significant leg of this journey.

One of the stated educational aims of the Doctorate in Health Science course at the University of Portsmouth is to enable health and social care practitioners involved in all aspects of health and social care science, an opportunity to explore their professional roles and implement research investigations to improve their contribution in a clinical, educational, managerial or service delivery setting. As I embarked on a professional doctorate programme as an adult learner, I hoped to build on the learning that I had already acquired. I hoped that towards the end of the programme, I would be equipped to be a better practitioner, researcher, trainer and manager, in that order.

This chapter is a reflection on my journey through the professional doctorate training, my role as a practitioner-researcher and the future. It describes my learning experiences over the last five years as a professional doctorate student in Health science. The reflection will involve scanning personal experiences throughout the journey for occasions where it seems likely that something significant has been learned. It is my personal story of my professional growth in many aspects of the practitioner knowledge domain, in lifelong learning as a health care science practitioner (HCSP), and as a trainer in specialist areas within the Neurophysiology Department at King's College Hospital, while pursuing a doctoral qualification.

## **8.2 The Journey**

### **8.2.1 Motivation**

As the course started, there were two driving forces for me. First, there was the motivation to achieve doctoral status; a personal desire and a driving force that was anchored upon the liberation that is brought about by higher qualification and the opening of new possibilities, not only professionally but also in life generally. Second, I was aware of my limitations in the profession and as person with interest in research and teaching activities; this was the perfect opportunity for me in cementing these aspirations. However, although the initial focus was the achievement at the end of the course, it became clear to me that the journey was as important as the destination.

### **8.2.2 Learning to learn**

Early in the course we undertook an interesting module on portfolio development. The personal development module helped me to identify myself as a learner and how best I could personally utilise the known learning models. This module helped me to see the need to write my own learning script based on my individual learning style. For that to work, it was necessary for me to be specific, not only in terms of where I wanted to go, but also what I needed to do to get there. In other words, professionally, I needed to create my own map that included my destination and the journey process to get there. I developed a road map with two standpoints: the present and future. These two

standpoints were defined by reflecting back on the learning I have already achieved to define my present standpoint and by looking forward to draw specific objectives to define the road to the future standpoint (Table 41).

**Table 41 Personal development roadmap**

WHERE AM I? Learning so far	HOW DID I GET THERE? Evidence of present learning and experience
WHERE DO I NEED TO GO? Aim/broad objectives	HOW DO I GET THERE? Specific/SMART objectives

### **8.2.3 Understanding research**

Before the beginning of the professional doctorate course, terms such as methodology, methods, quantitative, qualitative, mixed methods, systematic reviews etc., did not mean much. Learning the meaning of these terms and how they are applied in research was very instructional for me. Although I was reading research papers prior to embarking on the course, through the taught elements of the doctorate I am now able to gain more information by weighing the quality of the papers I am reading and sifting the materials to draw out what is relevant for my purposes.

The introduction of qualitative research methods was an amazing addition to my thinking about research. As I was carrying out a research project that involved understanding patients' views and experience of the procedure I was performing, the information I obtained would not have been gained through other methods, at least not in the same depth. The ability to apply quantitative and qualitative elements in a mixed method in my research has been very fulfilling, and something I hope to be able to use in the future.

### **8.3.3. Dealing with obstacles**

#### **Ethics:**

The thought of having to apply for ethics approval for my research project was the most unappealing undertaking. To my mind, going through the process of writing and rewriting the relevant documents ranging from proposal to protocol, then protocol to integrated research application system online application was daunting. Preparing the patients' information sheet and consent forms, and then speaking face-to-face with the ethics committee, was nerve-racking. Having heard from friends and colleagues at work how difficult and bureaucratic the process was I was determined to avoid it. I read and enquired about which studies and projects required ethics approval and which did not. I searched long and hard for a project that did not require approval. I found none. I then settled for a different idea. I had heard that it was possible to look for an ongoing large project where I could 'tag-in' and become part of the big project, with a view to using some of the data for my doctorate project. That way, I thought, I did not need a full ethics application but just an amendment, which would be dealt with by the principal investigator of the big study. Having found one study about sleep disturbance in movement disorders, I settled. However, this was short-lived as that project did not materialise. I then toyed with the idea of doing a systematic review, but my experience with the module on critical appraisal discouraged me from this consideration.

It was in one of my discussions with the research facilitators that the penny dropped. She said that doing a doctoral course was about responsibilities. It was about getting fully involved and directing oneself through the easy areas, as well as the more difficult ones. She said that going through ethics is part of this process. I let go of my fears and started the ethics process. Time was running out and the process was lengthy. On the day of my meeting with the ethics committee I left the boardroom room feeling as if I would never get approval for the study. When the outcome came, recommending several changes and not outright rejection, I was delighted, and with the corrections done I got full approval. I learnt two things from this experience. First, the nature of human beings is to dodge difficult issues and go for the easy option. I learned this is the wrong approach. It is not

about taking the easy way or difficult way, but what is important is to thoroughly evaluate what is required and make the necessary preparation. Second, I learnt that it is very easy to listen and act on what others say about issues etc. I learnt that although others' comments about the ethics process may be true, it was important to have the right attitude; now my view is that ethics committees are not there to reject studies or make life harder for researchers. In fact, they are there to approve studies, but only ensuring the patients or subjects are safe. Nevertheless, this dithering delayed my data collection for almost a year. Having gone through the process, I have already found myself offering positive contributions to colleagues who are struggling with this area.

### **Patients' recruitment**

Having looked at the referral pattern for patients to the telemetry unit at King's for the preceding year, and having worked out what percentage of those referrals required sleep studies, I was confident that recruitment would go smoothly. Therefore, it was shocking when, even after having gone through the ethics process, preparing the equipment and having set every other thing in place, a month went by and no referral was suitable. This threw me into a bit of a panic and I had to grapple with the challenges of recruitment. I even contacted a few sleep specialists who I knew referred patients to us for sleep studies. Introducing myself and the study, most were very supportive and I felt reassured that recruitment would go well. Before long, this also seemed like a false hope because by the second month I had only successfully recruited one patient. This did not auger well, considering that the plan was recruiting two per month. Once the study had started recruitment was slower than anticipated; nevertheless, progress was steady and, fortunately, I did not have any qualifying patient who declined to participate. The one thing I learnt from this process is that recruitment must never be taken for granted and allowance needs to be provided for, no matter how good the plan looks on paper.

### **Sacrifices**

For the majority of the last five to six years I was confined to what my family called the 'shed' at the end of our back garden, although I preferred to call it my 'academic' room.

The pattern was almost like clockwork: come home from work, have dinner and then go off to the shed. At work, it was no different. We have a tradition at work of going out most Fridays and chilling out after a long week of hard work. Most of the time this was a no-go for me. Likewise, during the day, over lunch, rather than join everybody in the common room and chat, I was confined to a corner, browsing through the Internet for academic, topical papers or something related. At times, I felt as though I was isolated from family and colleagues. So for me, things such as family, enjoying friends, nurturing relationships and enjoying life appeared as if they were being put off and sometimes I feared they might never be rediscovered. Many times, I was left wondering whether these sacrifices would be worth it in the end. Fortunately for me, I had overwhelming support from friends and family and I truly feel that I have more appreciation for my family and friends than before. For anyone embarking on the journey of a doctorate course, I dare say the sacrifices involved are real and must not be underestimated. They must be part and parcel of the planning process.

#### **8.4 Future**

When the course started, achieving professional status was a significant goal post or standpoint. Throughout the course, however, the experience became valuable and professionally rewarding in the process. Now that the end is near the question is what next? At the start of the professional doctorate, what seemed the ultimate standpoint, the destination of my lifelong learning journey five years ago, now appears like another start; what ought to have been the end of a journey looks like the beginning of another. I am thrilled at the prospect of completing the course successfully and I hope to enjoy this success, but I also realise that success is superficial. It makes one happy for a short while, but it isn't a lasting joy. No matter how much one achieves, accomplishes and acquires in life, there is always something more. The desire to move from stand point to standpoint, when one just achieved as fresh stand point, it leads one to explore around from the new vantage point. The notion of standpoint gives rise to the ascent of the mountain. From each new height, a new viewpoint (*Novak, 2009*).

So then, what next? My next phase is applying for registration as a Chartered Scientist (CSci) and hopefully membership in the Royal Society of Medicine. I would very much like to see more work done on home sleep studies and establish this service as standard practice. I am also very encouraged that two senior medical colleagues in the department have asked if I would be interested in two further studies; one study looking at sleep patterns in patients undergoing deep brain stimulation for epilepsy treatment and a second study looking at sleep changes in patients who have undergone surgical treatment for hypothalamic hamartomas. Aside from clinical practice, the professional doctorate journey has been most fitting not only in preparing me for a role in the wider society working with a charity/lobby group advocating for the interests of young girls trapped in child labour in my mother country but also provided me with qualifications that gives me leverage required in such an activity. I feel that the doctorate course has equipped me with the discipline, knowledge, skills and attitudes necessary to drive these aspirations to fruition.

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## Appendices

### Appendix 1 Patient information leaflet



King's College Hospital



NHS Foundation Trust

*Patient Information Sheet (version 2 dated 3rd May 2014)*

## 1 Study Title

Feasibility of Home Video Polysomnography (HVP)

Study Ref No: 129598

REC Ref No: 14/LO/0457

R&D Ref No: KCH14-121

## 2 Who is conducting the study?

I am a professional doctorate student at the University of Portsmouth working at King's College Hospital as a specialised Clinical Physiologist with a special interest in sleep disorders. As part of the doctorate programme, I will be undertaking a feasibility study exploring the viability of using home video polysomnography (HVP) in assessing patients with a special kind of sleep disorder called parasomnia. The research will be conducted within the department of Clinical Neurophysiology at King's College Hospital. Dr Rebecca Stores of the University of Portsmouth is my academic supervisor and Dr Nandini Mullatti of King's College Hospital is my work-based supervisor. Their contact details are listed at the end of this leaflet.

## 3 Invitation to take part

I would like to invite you to participate in this feasibility study assessing home video sleep studies referred to in the study as home video polysomnography (HVP). Before you decide, it is important for you to understand why the study is being done and what it will involve for you. This information leaflet will provide you with essential information about this procedure and your rights as a patient so that you can make an informed decision about your participation. Please talk to others about the study if you wish and feel free to ask questions if there is anything that is not clear or if you would like more information.

#### **4 Do I have to take part?**

Participation is entirely voluntary and you are free to withdraw at any time and without giving a reason. A decision not to take part or to withdraw at any time will not affect the standard of care you receive. If you decide not to take part in the study, you will be scheduled for standard laboratory based polysomnography. If you decide to withdraw after the study has started, any information obtained prior to your withdrawal that is deemed clinically useful will be retained with your medical records. You are not required to give an explanation for your withdrawal and any information you give will be entirely voluntary. We will not solicit information for withdrawal but any information relating to withdrawal will be noted to inform viability of this kind of service.

#### **5 What is the purpose of the study and why have I been chosen?**

Human beings spend their time either awake or asleep. These two wake and sleep states occur in a 24-hour cycle referred to as the sleep-wake cycle. These two states are separated by transitional periods where neither true wake nor true sleep is present. Sometimes, people experience disturbances in the sleep-wake cycle, particularly in the transitional periods where they present abnormal behaviours. This kind of abnormal behaviour is generally referred to as parasomnia. In some cases, this abnormal behaviour can cause serious problems to the individual, sleep partner or those within the vicinity of the person experiencing the disturbance. This particular group of sleep related disorders is commonly encountered in neurology and often requires tests in a sleep laboratory setting. This kind of test is called polysomnography (PSG). Laboratory settings for this study have certain limitations. We are hoping to explore other ways of assessing these disorders in patients' homes looking at the same features as in a laboratory-based setting. Your consultant has referred you to us at King's College Hospital Video Telemetry unit for laboratory-based PSG. From the information provided by your consultant in the referral letter, you would be suitable for the home video polysomnography study and that is why we have chosen to invite you to participate. We are aiming to recruit 30 patients.

#### **6 About the home video polysomnography**

This is a comprehensive sleep test, which will be carried out in the convenience of your home. Traditionally, the test is carried out in a sleep laboratory in a hospital setting. It is considered a necessary procedure to assess people with sleep problems or having undesirable events occurring in sleep.

The purpose of this study is to document the undesirable episodes occurring in your sleep, so as to better understand them and to help determine the best way to treat them.

The quality of data obtained will be assessed and the clinical information obtained from the recorded data will be communicated to your referring consultant. If the data obtained is considered to be of poor quality, or insufficient to make a clinical decision, you will be offered the opportunity to undergo the standard video PSG in the hospital laboratory.

During the procedure, we will record various biological signals using electrodes/sensors and behavioural features occurring in sleep via an audio/visual camera (Figure 1) over 2-3 days.

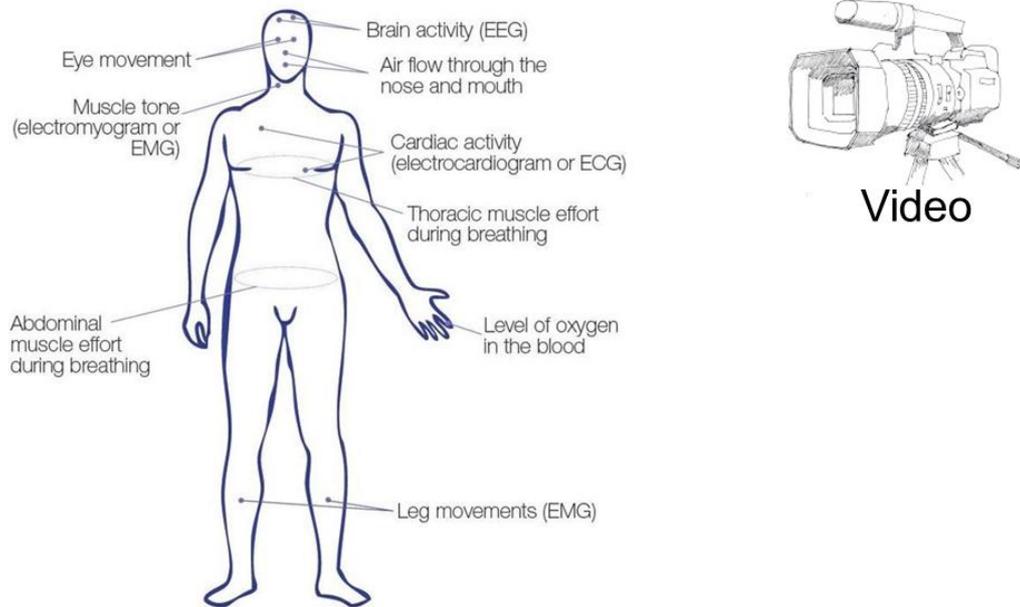


Figure 1 Areas where sensors or electrodes will be connected and camera position

The recording will be continuous throughout the night and day. As a result of the restriction that might be associated with the recording, it would be very useful if a partner or nominated care-provider of your choosing were available during the study period. However, if no one is available, it is still possible to participate because the recording equipment can be disconnected for brief periods when necessary (Figure 2). The researcher will show you how to disconnect and reconnect.



Figure 2 Headbox with wires in special jacket and connecting cables

## **7 What will happen to me if I take part?**

- i. If you decide to take part in the study, the researcher will explain the test and answer any questions.
- ii. You will be asked to sign a consent form.
- iii. Electrodes and other recording devices will be applied with special glue or adhesive tape to different parts of the body and then passed behind the body.
- iv. These will then be attached to a small recorder box. The box with electrodes will be secured in the pocket of a special jacket that will be provided (Figure 2).
- v. You should not have a bath or shower, or wash or comb your hair once you have the electrodes attached.
- vi. You will be asked to press a special button when you go to sleep (this is the time when you decide to settle in bed and are ready to sleep, i.e., lights out) and then again when you wake up in the morning (this is the time you finally awaken, i.e., lights on).
- vii. On the last day of recording the electrodes will be taken off using a solution to dissolve the special glue.
- viii. The recorded data will be taken back to the hospital for analysis. The data will be evaluated to ascertain data quality and sufficiency for clinical utility. If the data obtained is considered to be of poor quality or is insufficient, you will be offered an opportunity to undergo a standard video PSG in the hospital laboratory.
- ix. In addition to sleep related data, the researcher will also conduct a two-part interview at the start of the procedure and at the end. Each discussion will last 30 minutes. This discussion will be tape-recorded. The interview will explore your views and perspectives of the process and experience of having home video polysomnography.

## **8 What do I have to do?**

- i. Make space in your room for the recording equipment.
- ii. You will need to be within 20 feet of essential areas such as the toilet. To reduce the risk of tripping on the cables, together with you and your partner, the researcher will discuss and carryout a risk assessment to identify possible safety issues and plan for equipment layout.
- iii. Your hair should be clean and “undone” to allow the electrode application.
- iv. Wear comfortable/baggy clothes that will allow access for electrode and/or sensor application and to allow discreet video recording of the whole body.
- v. Take your regular medications, if any, as usual.
- vi. The researcher will be contactable any time during the course of the recording for advice. The contact telephone number is 07784710667. You will, however, be under your GP for all other medical issues as usual.

## **9 Will my taking part in this study be kept confidential?**

Yes. The researcher is committed to ensure that:

- i. You know and feel that information you provide in the course of this study is safe and treated in confidence.
- ii. You have the right to know how the information you give will be used.
- iii. The researcher will act and abide within the law, NHS guidelines and King's College Hospital Trust's policy in dealing with your information. Specifically, the data will be seen only by authorised persons, and where possible data will be anonymised and confidentiality will be maintained at all times.
- iv. You are well informed and consent is sought about the data that will be recorded.
- v. You have a right to ask the Trust to allow you to see and correct any medical information about you and may claim compensation for inaccuracy, loss or unauthorised disclosure.

#### **10. How information about you will be obtained and handled:**

The bulk of the information will be obtained from the test, which will include biological signals, and audio and video recording. The equipment is designed to record video and audio separately. Both the camera and the microphone will be mounted on a pole attached to the trolley housing the recording equipment (Figure 3). The investigator will explain and show you how you can adjust the position and direction of these when necessary.



Figure 3 Assembled system with computer, camera and monitor

- i. The investigator will have information sent by your consultant in the referral letter.

- ii. The investigator will also have access to clinical information stored in the hospital record system. This will only be accessed if it is required for the study.
- iii. The investigator may need to obtain further information from you or your close relative/partner. Please let the researcher know if you have concerns about this.
- iv. All information which is collected about you during the course of the research will be treated in accordance with King's College Hospital's data protection policy, and the Data Protection Act 1998 and the rights you have under this Act. In particular, we will only use equipment that has been approved by the King's College Hospital Trust; data will be copied on encrypted/password protected media devices; transportation of equipment and data will be by the Trust's authorised transport and in custody of the investigator during transportation, and that it will be securely stored in the hospital for at least eight years.

### **11 How we use your information:**

- i. Information obtained about you, will be used for the feasibility study and may also be used for your clinical evaluation.
- ii. It may be used for teaching, further research, and clinical audit or for management related issues.

### **12 Researcher's expectations:**

- i. You fully understand the nature of the study and what it requires of you.
- ii. You will cooperate to ensure the test runs smoothly.
- iii. You will treat the researcher and other staff attending your home with respect.
- iv. You will respect and treat our equipment with care and you will ensure that other members of your family or friends do not interfere with the data being recorded.
- v. You will let the researcher know if you have concerns or feel your confidentiality or privacy is being compromised.

### **13 What are the other possible disadvantages and risks of taking part?**

There are no known risks or after-effects from this test but some minor discomforts and inconveniences might happen such as:

- i. Redness of skin from sensors, paste/scrub and/or tape.
- ii. Sleeping with unusual recording sensors attached to your body.
- iii. Being restricted within the recording area.
- iv. Some lighting may be needed overnight for good video picture.
- v. Some compromise on your privacy (no video recording is done in the bathroom).
- vi. Not able to bath or shower during the recording.

#### **14 What happens if there is a problem?**

There is no special compensation arrangement for these expected discomforts and/or inconveniences, but if you are harmed due to someone's negligence you may then have grounds for legal action, however you may have to pay your legal costs.

King's College Hospital NHS Foundation Trust has agreed that if you are harmed as a result of your participation in the study, you will be compensated provided that, on the balance of probabilities, an injury was caused as a direct result of the intervention or procedures you received during the course of the study. These special compensation arrangements apply where an injury is caused to you that would not have occurred if you were not in the trial. These arrangements do not affect your right to pursue a claim through legal action.

However, regardless of this, if you wish to complain or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms should be available to you. Please contact the Patient Advisory Liaison Service (PALS) if you have any concerns regarding the care you have received, or as an initial point of contact if you have a complaint. The PALS contact details are listed at the end of this leaflet.

#### **15 What are the possible benefits of taking part?**

We expect the information obtained in the study will be sufficient and that there will be no need to undergo a laboratory based PSG. We cannot, however, guarantee that this will be the case. Some of the benefits of home polysomnography include:

- i. A shorter waiting time as there are long waiting times for lab based testing.
- ii. The convenience of having it carried out in your home; hence there is less disruption to your daily activities.
- iii. Flexibility in arranging when the test can be done.
- iv. Cut down on travel costs and other expenses associated with being away from your home.
- v. The study reflects more natural environmental situations.

#### **16 Who is organising and funding the research and where was it reviewed?**

The research is part of professional development leading to a Professional Doctorate qualification. The University of Portsmouth is providing the academic elements and the Department of Clinical Neurophysiology at King's College Hospital the clinical support. The feasibility research project is part of the Clinical Neurophysiology patient care delivery Service improvement initiative. It is a non-portfolio research project with no external funding.

As this feasibility study aims to explore whether HVP n is viable for clinical utility with the possibility of eventually being used as a clinical service for the benefit of patients, input from a relevant patient group was sought, particularly with regard to the qualitative strand and patient information. In this regard, help from members of Restless Leg Syndrome (UK) was sought and their views and perspectives were considered in the design of this study.

The study has been reviewed and approved by King's College Hospital Research & Development and NRES Committee London - Dulwich.

#### **17 Contact Details for further information:**

- i. The researcher/student: Peter Muthinji-

Highly Specialised Clinical Physiologist (Neuro)

Dept. Clinical Neurophysiology

4<sup>th</sup> Floor, Ruskin Wing

King's College Hospital

Demark Hill

London SE5 9RS

Phone: 020 32994672 (work)

07784710667 (any time during the recording period)

Email: [pmuthinji@nhs.net](mailto:pmuthinji@nhs.net)

- ii. Work Based Supervisor: Dr Nandini Mullatti

Consultant Clinical Neurophysiologist

Dept. Clinical Neurophysiology

4<sup>th</sup> Floor, Ruskin Wing

King's College Hospital

Demark Hill

London SE5 9RS

Phone: 020 32993151

Email: [nandini.mullatti@nhs.net](mailto:nandini.mullatti@nhs.net)

iii. Academic Supervisor: Dr Rebecca Stores

Associate Head (Research and Knowledge Services)

School of Health Sciences and Social Work

University of Portsmouth

James Watson West

2 King Richard 1<sup>st</sup> Road

Portsmouth, PO1 2FR

Tel: 023 9284 4440 ext 4425

Email: [Rebecca.stores@ports.ac.uk](mailto:Rebecca.stores@ports.ac.uk)

iv. Sponsor Representative: Dr Zoe Harris

R&D Dept. Manager

King's College Hospital

161 Denmark Hill

London, SE5 8EF

Phone: 020 3299 1981

Email: [z.harris@nhs.net](mailto:z.harris@nhs.net)

v. Patient Advice & Liaison Service: Patient Advice and Liaison Service (PALS)

King's College Hospital

Denmark Hill

London SE5 9RS

Phone: 020 32993601

Email: [kch-tr.PALS@nhs.net](mailto:kch-tr.PALS@nhs.net).





King's College Hospital



NHS Foundation Trust

**Partner's Information Sheet (Version 2 dated 25th July 2014)**

**Study Title:** Feasibility of Home Video Polysomnography (HVP).

Study Ref No: 129598  
REC Ref No: 14/LO/0457  
R&D Ref No: KCH14-121

**2. Introduction**

I am a professional doctorate student at the University of Portsmouth working at King's College Hospital as a specialised Clinical Physiologist with a special interest in sleep disorders. As part of the doctorate programme, I will be undertaking a feasibility study exploring the viability of using home video polysomnography (a form of sleep study test) in assessing patients with a special type of sleep disorders referred to as parasomnias. The research will be conducted within the Department of Clinical Neurophysiology at King's College Hospital. Your partner, who was referred to us for this test, has agreed to participate in this feasibility study.

As the test is being carried out in your home, it is important for you to understand why the study is being done and what it will involve for you as the partner of a participant. This information sheet is meant to provide you with essential information about the procedure and how this might affect you. Please talk to your partner about the study if you wish and feel free to ask questions if there is anything that is not clear or if you would like more information.

**3. About the home video polysomnography**

This is a comprehensive sleep test, which will be carried out on your partner at your residence. Traditionally, the test is carried out in a sleep laboratory in a hospital setting. The purpose of the test is to document the undesirable episodes occurring in sleep, so as to better understand them and to help determine the best way to treat them. The test is considered a necessary procedure to assess people with sleep problems or for those having undesirable events occurring in sleep. During the procedure we will record various biological signals from various parts of the body (Figure 1). We will also record video and sound. The recording will be continuous throughout a 24-hour period for 2-3 days. The reason for recording during the daytime is to assess if events occurring at night affect daytime functioning such as being unusually sleepy during the day.

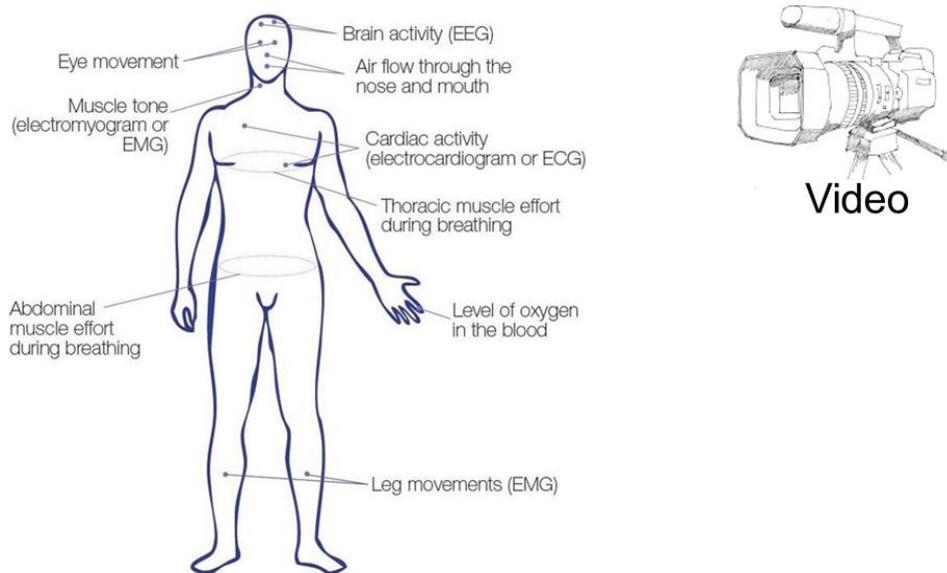


Figure 1 Areas where sensors or electrodes will be connected and camera position

#### 4. Privacy

Although the video recording is intended for your partner, it is difficult to guarantee that you will not be included in the recording when you are within the vicinity of the recording system. In particular, there will be some compromise on privacy, as recording will be carried out in the bedroom, which for most people is a private and personal space. The image of the picture being recorded will be visible on the screen (Figure 2) and your partner will be shown how to move away from the camera temporarily when necessary. As the test will include video recording some lighting may be needed overnight for a good video picture, and this might be an inconvenience for some. For these reasons you may choose to sleep in another room overnight; however, if you do not, please be aware there may also be times when you too will be visible on camera. We advise suitable bedtime attire to maintain modesty.

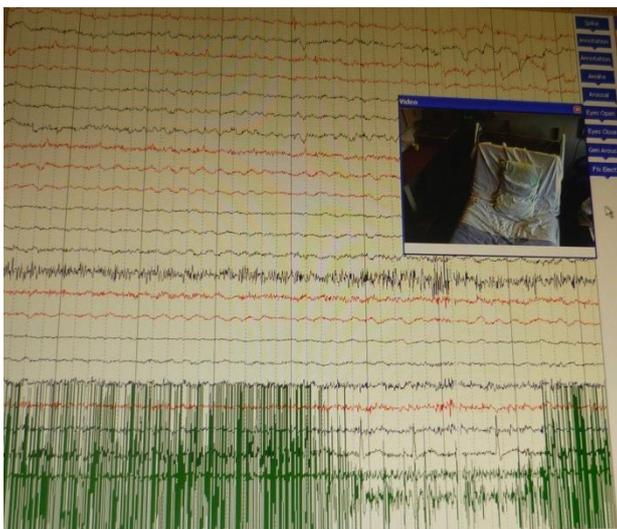


Figure 2 An example of what will be displayed on the screen during the recording

## 5. Safety

To reduce the risk of tripping on the cables, the researcher will discuss this with you and your partner and carry out a risk assessment to identify possible safety issues and plan for equipment layout. The recording equipment will be on a mobile trolley (Figure 3). Please help your partner to make space in your room for the recording equipment.



Figure 3 Assembled system with computer, camera and monitor

## 6. Inconvenience

Since your partner will be restricted to within a distance of 20 feet, you are likely to be required to help undertake chores that your partner may be unable to do due to this mobility restriction. In cases where it is absolutely necessary to move outside of the 20 feet restriction perimeter, there is a facility to allow temporary disconnection by detaching the cable from the little box containing the wires/sensors (Figure 4). The researcher will show your partner how to disconnect and reconnect the cable.



Figure 4 Headbox with wires in special jacket and connecting cables

### **7. Confidentiality**

The researcher will visit daily to check the recording system and collect the recorded data. The recorded data will be copied to an encrypted portable disc and transported by hospital-approved transport. Information obtained will be used for the feasibility study and may also be used for your partner's clinical evaluation. It may be used for teaching, further research and for clinical audit or management issues. Where you appear as a 'bystander' on the video, effort will be made to blur the picture; however, we may not be able to obscure sound, and it is important you are aware of this, as this will be stored together with your partner's medical records in a hospital secure server.

### **8. Review**

The study has been reviewed and approved by the King's College Hospital Research & Development and NRES Committee London - Dulwich.

### **9. Contacts**

Please do feel free to contact the researcher in case you need more information or clarification. The researcher will be contactable at any time during the course of the recording for advice on telephone 07784 710667 or via email: [pmuthinji@nhs.net](mailto:pmuthinji@nhs.net)

**Appendix 3 Patient consent form**

Study Ref No: 129598; REC Ref No: 14/LO/0457; R&D Ref No:

**Please initial box to indicate agreement**

Your consent	Initials
I confirm that I have had time to read carefully and understand the patient information sheet version 2 dated 3 <sup>rd</sup> May, 2014, provided for this home video polysomnography	
I confirm that I have had the opportunity to discuss the research procedure and ask questions and I am satisfied with the answers and explanations that I have been provided with.	
I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without my medical care or legal rights being affected.	
I understand that relevant sections of any of my medical notes and data collected during the study may be looked at by responsible individuals from the University of Portsmouth, from regulatory authorities, or from King's College Hospital NHS Foundation Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	
I understand that video recording may capture other people within the recording area and that they are aware of the possibility and have no objection.	
I understand that the video recording may be used for research and may also be used for teaching purposes and I agree to such use.	
I agree to take part in this feasibility study procedure.	
I confirm that I have received a copy of the patient information sheet version 2 dated 3 <sup>rd</sup> May 2014.	

**Patient**

Name (capital letters) \_\_\_\_\_

Signature \_\_\_\_\_ Date \_\_\_\_\_

**Authorised Person Obtaining Consent**

Name (capital letters) \_\_\_\_\_

Signature \_\_\_\_\_ Date \_\_\_\_\_

#### Appendix 4 Partner consent form

Study Ref No: 129598; REC Ref No: 14/LO/0457; R&D Ref No: KCH14-121

Please **initial box** to indicate agreement

Your consent	Initials
I confirm that I am aware that my partner has agreed to take part in a feasibility study involving video recording in our home.	
I confirm that I have had time to read carefully and understand the information sheet for partners (version 1 dated 3 <sup>rd</sup> May, 2014) provided for this home video polysomnography study.	
I confirm that I have had the opportunity to discuss and ask questions about the research procedure and how this might affect me and I am satisfied with the answers and explanations that I have been provided with.	
I understand that the video recording intended for my partner may capture my image and I have no objection to this.	
I understand that the video recording of my partner may be used for teaching purposes and that I am aware such a video section may include my image.	
I agree to help my partner as required during the course of this feasibility study procedure.	
I confirm that I have received a copy of the partner's information sheet (version 1 dated 3 <sup>rd</sup> May 2014).	

Name (capital letters) \_\_\_\_\_

Signature \_\_\_\_\_ Date \_\_\_\_\_

Relationship to the patient \_\_\_\_\_

#### Authorised Person Obtaining Consent

Name (capital letters) \_\_\_\_\_

Signature \_\_\_\_\_ Date \_\_\_\_\_



## Health Research Authority

NRES Committee London - Dulwich

Health Research Authority  
Skipton House  
80 London Road  
London  
SE1 6LH

Telephone:

020 7972 2582 16 June 2014

Mr Peter Muthinji

Dept. of Clinical Neurophysiology

King's College Hospital

Denmark Hill, London

SE5 9RS

Dear Mr Muthinji

**Study title:** A feasibility study assessing home video polysomnography (HVP) as an acceptable diagnostic procedure for adult patients with parasomnias  
**REC reference:** 14/LO/0457  
**IRAS project ID:** 129598

Thank you for your letter of 13th May 2014, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Vice-Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact the REC Manager, Stephanie Hill, nrescommittee.london-dulwich@nhs.net.

### Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised subject to the conditions specified below.

## Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

**You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.**

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

*Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.*

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

*Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.*

*For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.*

*Sponsors are not required to notify the Committee of approvals from host organisations*

### ***Registration of Clinical Trials***

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first

participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity, e.g., when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett ([catherineblewett@nhs.net](mailto:catherineblewett@nhs.net)), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

**It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).**

## Ethical review of research sites

### NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

### Non-NHS sites

The Committee has not yet completed any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not, therefore, apply to any non-NHS site at present. We will write to you again as soon as an SSA application(s) has been reviewed. In the meantime, no study procedures should be initiated at non-NHS sites.

## Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
GP/consultant information sheets or letters	1	03 May 2014

Other [CV of supervisor Dr Rebecca Stores]		26 November 2013
Other [CV for supervisor - Dr Mullatti]		19 March 2014
Other [CV for supervisor Dr Louise Turner]		
Participant consent form [Patient]	2	03 May 2014
Participant consent form [Partner]	1	03 May 2014
Participant information sheet (PIS) [Patient]	2	03 May 2014
Participant information sheet (PIS) [Partner]	1	03 May 2014
REC Application Form	129598/5719 11/1/912	04 March 2014
Research protocol or project proposal	1	08 October 2013
Response to Request for Further Information		13 May 2014
Summary CV for Chief Investigator (CI)	Student Mr Muthinji	26 October 2013

## Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

## After ethical review

### *Reporting requirements*

The attached document "*After ethical review – guidance for researchers*" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

### *Feedback*

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known, please use the feedback form available on the HRA website:

<http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/>

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

<b>14/LO/0457</b>	<b>Please quote this number on all correspondence</b>
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With the Committee's best wishes for the success of this project.

Yours sincerely

A handwritten signature in black ink, appearing to read 'P. J. Hill'.

**Mr Colin Standfield Vice-Chair**

Email: [nrescommittee.london-dulwich@nhs.net](mailto:nrescommittee.london-dulwich@nhs.net)

*Enclosures:* "After ethical review – guidance for researchers" [SL-AR2]

*Copy to:* *The Research Office, King's College Hospital NHS Foundation Trust*

## Appendix 6 KCH14-121 R&D approval letter

22/07/2014

### The Research Office

Mr Peter Muthinji  
King's College Hospital  
Clinical Neurophysiology  
Ruskin Wing  
4th Floor  
London  
SE5 9RS

Kings College Hospital NHS Foundation Trust  
First Floor 161 Denmark Hill,  
London, SE5 8EF  
Direct tel: 020 3299 1980  
Direct fax: 020 3299 5515

[www.kch.nhs.uk/research](http://www.kch.nhs.uk/research)  
[kch-tr.research@nhs.net](mailto:kch-tr.research@nhs.net)

Dear Mr Peter Muthinji,

**Study Title: A feasibility study assessing home video polysomnography (HVP) as an acceptable diagnostic procedure for adult patients with parasomnias**

**Ethics ref: 14/LO/0497**

**Sponsor: KCH**

**Campus: - Denmark Hill**

**Study duration: 1 year and 3 months**

**Target Recruitment: 30**

**Protocol Version: v1**

On behalf of **King's College Hospital NHS Foundation Trust**, I am pleased to inform you that your project is approved and you may proceed.

The study has been registered as **KCH14-121**. Please quote this reference in any communications with the Research Office regarding your project.

**As a Trust we are required to meet the national NIHR 70 calendar day metric (valid submission to 1st patient consented). I can confirm that at the date of R&D approval the clock is at 4 days; therefore, to achieve the metric you need to consent your first patient by 26-Sep-14.**

All approved documents are listed at the end of this letter. Please ensure that any amendments to the documents or changes to the study team are notified to the office.

**Investigator Responsibilities:**

- ***You are expected to recruit to time and target. A condition of the approval is to notify the Research Office of the date of first recruitment at the above email address.***
- The approval is conditional on the project being conducted as described within the application. The project must follow the agreed protocol and be conducted in accordance with all Trust Policies and Procedures - especially those relating to research and data management.
- You must notify the office of all changes to the project, such as amendment to protocol and changes in study team. An end of study report and copies of the yearly REC report should be submitted to R&D.
- You are responsible for ensuring that good research governance, conduct and practice are maintained throughout the duration of the study.
- The Trust maintains oversight of all active projects and you may be subject to review and audit at any point by internal or external bodies.
- If the project is a clinical trial under the European Union (EU) Clinical Trials Directive, the EU legislation must be complied with.

**If appropriate, it is recommended that you register with the Current Controlled Trials website;**  
<http://isrctn.org/>

The Research Office will support you throughout the duration of your project. Please contact us at the address above if and when you require further information or guidance.

We wish you every success with your project.

Yours sincerely,



Kirsty Hedditch

**List of Approved Documents:**

<b>File Name</b>
05 HVP Protocol Application - version 1, 8th Oct 13 revised 9 April.doc
06 HVP Patient Information Leaflet - version 2, 3rd May 2014.doc
07 HVP Patient Consent Form - version 2, 3rd May 14.doc
08 HVP Partner's Information Sheet - version 1, 3rd May 14.doc

09 HVP Partner's Consent Form - version 1, 3rd May 14.doc
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10 HVP GP Letter - version 1, 3rd May 2014.doc
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V2 March 2014

## Appendix 7 HVP qualitative interview questions

### Part 1: 30 minutes

*“As you already know, I am working in the department of Clinical Neurophysiology at King’s College Hospital. I am currently enrolled at the University of Portsmouth in a doctoral programme. My study interest is sleep medicine. I am looking into doing sleep studies in patients’ home. So to get us going;*

Tell me how you found out that you had a sleep problem?

What were your thoughts when you discovered you had sleep problems?

Can you tell me how you learned about home sleep studies and what were your thoughts?

Tell me about home sleep studies and what are your views about them.

### Part 2: - 30 minutes

As we discussed earlier, this session is a follow up on the interview we had at the start of the procedure:

5. How was it for you to have the study done in your home?
6. What particular aspects did you find useful in having the procedure at home?
7. Tell me about the concerns you might have about the procedure at home and how this evolved in the course of having the study.
8. Can you tell me what areas can be improved to make home study a more positive experience for patients?
9. Do you have anything to add or ask before we end this interview?

*“Thank you for participating in this interview. The contents will be analysed and together with interview of the other patients, we hope to get a good idea of the general view on this procedure. We will be happy to let you know of the outcome if you wish”. End*



## Appendix 8 Organising transcribed data

	Question and answers	A	B	C
1	<b>PM: Tell me about the problem that is making us do this test</b>			
2	<b>KW:</b> Eh, so the main issue was the massive chronic fatigue [...] obviously the	chronic fatigue		
3	sleep patterns have [...] let's find out what the sleep patterns are like [...] make me	sleep patterns		
4	feel during the day [...] not sleeping well and my husband obviously said I jerk a lot	jerk, effect on spouse	impact	
5	during the night.			
6	<b>PM: What was happening during the day</b>			
7	<b>KW:</b> Ehm, so this is the problem [...] changed me now, I would say, over the last			
8	Year. It started again, December last year [...] so it was a matter of massive fatigue, a little	massive fatigue		
9	ache all over; ehm, feel like you got flue symptoms [...] ehms, chronic pain, ehm,	chronic pain		
10	literally concentration level is very minimal [...] unable to concentrate and daily tasks	poor concentration	impact	
11	were a massive, massive effort. Like smallest things which people take for	massive effort to do simple things		
12	granted were difficult, I needed lots of help from family.	need help from family	impact	
13	<b>PM: but in terms of sleep...</b>			
14	<b>KW:</b> you wake up tired, you wake feeling [...] and I think achiness was really bad –	wake tired	impact	
15	just makes you feel really ill. Actually, the jerking at night, obviously I was not	nocturnal jerking	impact	
16	aware I was doing it. It was my husband who told me. I try to be aware	effect on spouse	impact on others	
17	when I am falling to sleep. I am aware of that but obviously when I am asleep it is			

18	not easy.			
19	<b>PM: What impact has this had on you and family life?</b>			
20	<b>KW:</b> It has affected every aspect of my life. My problems are I don't sit down very	life style affected	impact	
21	Easily, so I can't relax very easily. I am all the time going from back [...] And just			
22	relying, as I say, on my family members to do things and obviously looking after	no independence	impact	
23	our Aby.			
24	<b>PM: How important was it for you to have this sorted?</b>		impact	
25	<b>KW:</b> Massive, massive especially when you can't go to work, your life just gone	life gone		
26	down overnight [...] you just realise how much impact it has on you [...] what you	great impact on life		
27	take for granted in life			
28	<b>PM: Tell me how you came to know about the test.</b>			
29	<b>KW:</b> Ehm, I seen the neurologist, obviously I just mentioned to him about my			
30	sleep pattern. Honestly I have been doing so much research anyway because	prior knowledge		
31	nobody could tell me what was wrong, so I needed to find out how I can help	Frustration		
32	Myself [...] so I have read book after book about chronic fatigue [...] and yes lots and			
33	lots of supplementary vitamins I took to try to help things, and lots of consultants			
34	I have seen. I could mention to them about the sleep cycle I have overnight. So,			
35	are there 4 stages of sleep or is it five? OK. And the awareness that my husband	jerk, reported by husband		
36	says I jerk a lot. And it was waking him up quite			

	a lot. So it is like when people			
37	snore. Obviously I don't snore so much. Yah, waking him up by jerking. But,	effect on spouse		
38	Ya.			
39	<b>PM: Tell me what you know about sleep studies.</b>			
40	<b>KW:</b> I just mentioned to the neurologist that obviously my situation in			
41	general [...] could my sleep pattern be affecting my day to day [...] Ya, and obviously			
42	about the jerking at night. He said [...] I requested if would have a sleep study (I DON'T UNDERSTAND THIS) [...] I	self-request		
43	said to him [...] would help if I had done a sleep study and he said yes that's fine I can			
44	request one for you. So he was happy to do that [...] I think its because when you go			
45	round in circles and vicious circles trying to find out what is wrong and actually	control of her problems		
46	you are not getting any answers [...] I think you need to take things further don't you?			
47	<b>PM: ya ya, sure.</b>			
48	<b>KW:</b> because you are not getting anywhere, at least I have my appointment in			
49	May for my chronic fatigue in King's and I am still waiting to be seen because it is			
50	all about funding and it all about [...] ya [...] the research – funding and it needs to			
51	be funded by the actual individuals [...] I am still waiting.			
52	<b>PM: You said you heard about sleep studies and you requested [...] How</b>			
53	<b>about knowing they can be done at home? Tell me a bit about that.</b>			

54	<b>KW:</b> Eeh, I was not aware that you could do it at home [...] He said obviously you	unaware of HVP		
55	could do it at King's and I said it was fine, and then one afternoon I think one of			
56	your team called and said you were trialling sleep studies at home rather than in			
57	the hospital and I was quite surprised. Then they said it will take readings during	Surprised		
58	the day and at night as well [...] being trapped obviously in a room is [...] is not very	being trapped in a room		
59	good [...] when I was so unwell [...] It would not have bothered [...] you think ,Oh my			
60	God, I'm going to sit in a room [...] I will keep myself occupied [...] I then, I said, you			
61	Know [...] it does not give a true reflection of your day because in a day			
62	you do lots and lots of things and being in a room actually you are not going to			
63	be your normal [...] It does not give a true reflection, because wild you be as tired (I DON'T UNDERSTAND THIS)	not true reflection		
64	will you [...] But we'll see, we'll see, we can only see [...] But I would rather be here	rather be at home than in hospital	environment	
65	than the hospital.			
66	<b>PM: Did you have any concerns when you were told this test can be done at</b>			
67	<b>home?</b>			
68	<b>KW:</b> No, no. I was obviously surprised when she said [...] so where is your bedroom?			
69	Where is your toilet? [...] and things like that [...] I did not realise [...] oh in the (WHAT DOES THIS MEAN?) bedroom for			
70	3 days [...] It is actually not as bad because it is Monday afternoon and you will be			
71	back Wednesday morning [...] It's obviously working out when my husband was going to	flexibility of appointment	flexibility	

72	be around, otherwise I was not going to be able to get a drink or something to			
73	eat [...] and that is the difference with being in the hospital [...] they do things for you			
84	don't they [...] here, obviously, I have to rely on when my husband has days off and			
75	my mother in law obviously has to take A to school [...] things that you obviously			
76	take for granted [...] I have been trying to work out what I need to do.			
77	<b><u>Second part: On the day of finishing the test</u></b>			
78	<b>PM:</b> So K, what was your experience in having the test done here at home?			
79	<b>KW:</b> So, in general, you mean being done here rather than in hospital?			
80	<b>PM:</b> Yes			
81	<b>KW:</b> So, even if there has been a little bit of pain, it has definitely been better at	definitely better		
82	home than in hospital. I think it [...] has inconvenience [...] just like you – you have the	less inconvenient		
83	inconvenience of coming here [...] Obviously, I can get on and do some things in the	do house work		
84	bedroom, ehm, it is not too bad. I think it would have been harder if my toilet was			
85	not there. Obviously it would have been, I do not know what would have			
86	happened if my bathroom would have been downstairs.			
87	<b>PM: Probably would have meant disconnecting temporarily.</b>			
88	<b>KW:</b> Disconnect every time [...] but in general my husband had to look after			
89	Me (chuckles) [...] He has been fine, but by yesterday afternoon he was thinking [...]	inconvenient to spouse		

90	how many teas do I have to bring you? Why, I keep on calling him? [...] I need a little			
91	Bell ( laughter)			
92	<b>PM: He was getting a bit tired?</b>			
93	<b>KW:</b> Ya, he was getting a bit fed up with [...] Eem, no he was fine. In general, ya,	spouse fed up		
94	even in hospital the lights would have been on anyways and you don't sleep very	light inconvenient		
95	well in the hospital. I think you are better off at home	home better	environment	
96	<b>PM: You think you slept better?</b>			
97	<b>KW:</b> Definitely, I slept better here than what I would have done in hospital,	slept better		
98	Definitely [...](pause) and it is not long either cause obvious you did not get here till			
99	Monday afternoon and now this morning, so it was really only yesterday			
100	<b>PM: So the timing was...</b>			
101	<b>KW:</b> Yes, the timing is good [...] Yes, if you really need to have things done [...] but if	good timing		
102	you going, if you going to the hospital, you got to be there in the morning, you	hospital arrangement too restrictive	convenience	
103	have got to wait for people to come round, don't you? And I think it would have			
104	been long winded in the hospital.			
105	<b>PM: Are there any particular aspects that you found useful?</b>			
106	<b>KW:</b> Yes, obviously I think it is nice to [...] even if I can't do much with my little boy, it			
107	is nice to be here for my boy and be able to chat and everything [...] Oh ya, I must	not being separated from family		
108	apologise for I just realised how many			

	conversations I have had with different			
109	people on the camera and I forget I'm being filmed. It would be good to know,			
110	Obviously, what my sleep stages are and the two comparisons, that one was good.			
111	<b>PM: Comparisons of ...</b>			
112	<b>KW:</b> One night with tablets and one night without.			
113	<b>PM: What do you think of your sleep on the 2 nights then?</b>			
114	<b>KW:</b> Ya, it seems like I woke up more. Ya, and the things were becoming a little bit	electrodes itchy		
115	itchy and the tape was pressing hard. So if the people did not want it at home,			
116	would they still be able to do it in the hospital?			
117	<b>PM: Yes.</b>			
118	<b>KW:</b> They can do that [...] but obviously they have got a longer waiting list.			
119	<b>PM: Eeh, its probably more or less the same.</b>			
120	<b>KW:</b> It is matter of choice, because obviously, midweek people would be at work,			
121	obviously, my husband has a long weekend off every so often so it worked so	may not work if one is alone at home		
122	well those 2 days; but generally people work don't they? Otherwise if no one			
123	is around, it would have to be in the hospital.			
124	<b>PM: Cause they need to take care of you?</b>			
125	<b>KW:</b> Yes, unless they bring loads of food [...] I could be prepared and bring lots of			
126	things that I need upstairs			
127	<b>PM: What aspects did you find particularly positive?</b>			

128	<b>KW:</b> Oh yaa, it was just being able to be here other than the inconvenience of being in the			
129	hospital. In the hospital, people then come to visit you and that is inconvenient	difficulty of visiting in hospital, travel	financial	
130	for them as well. Especially, King's is not that near. In general, it is fine. Timing it			
131	is fine, if it would have gone for much longer.	timing better, test sooner		
132	<b>PM: Thinking back over the last 2 days of recording, are there things you</b>			
133	<b>think could have been improved to make it better experience for you?</b>			
134	<b>KW:</b> Ahh, not really. Its fine. Ya, you (dis)entangled the wire yesterday. I did not			
135	Realise [...] ya, when it entangles you can't move around much. The lighting [...] yes,			
136	obviously you are used to sleeping without a light on. I wore a mask last night but it	equipment a bit inconveniencing		
137	is not the same. I think in a little way, the box (head-box), felt like it was hanging.			
138	and overnight it is not the best to sleep on.			

Appendix 9 Letter to GP

**GP letter version 1 dated 3<sup>rd</sup> May 2014**

Date: \_\_\_\_\_

Dear Dr \_\_\_\_\_

RE: Feasibility of Home Video Polysomnography (HVP)

Study Ref Number 129598

<u>Patient's Name</u>	<u>DOB</u>	<u>Hospital number</u>
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I am writing to inform you that your patient, named above, who was referred for video polysomnography with provisional diagnosis of parasomnia has agreed to participate in a feasibility study to be carried out at the Department of Clinical Neurophysiology of King's College Hospital.

Video polysomnography is normally done in a laboratory setting. However, laboratory based polysomnography evaluates sleep patterns in an unnatural environment, requires changes of individual's sleep routines and are often expensive. The purpose of the study is to explore the feasibility of performing these tests in the patients' homes.

From the information provided by the consultant in the referral letter, the patient would be suitable for the home video polysomnography study and that is why we made the invitation to participate. The study is expected to recruit 30 patients within a period of 15 months. Each patient will undergo continuous 24-hour recording of video polysomnography for 2-3 days in their own homes.

Performing polysomnography at home carries an element of change in standards of care, as these tests are normally carried out in the laboratory. Recorded data will be evaluated to ascertain quality for clinical utility. Those patients whose data is considered insufficient will be offered an opportunity to have a standard laboratory test.

The study is part of a professional doctorate qualification for the investigator and is being supported by the Department of Clinical Neurophysiology at King's College Hospital as part of department's patient service improvement initiative.

I have enclosed a copy of the Patient Information Sheet for your reference. However, if you have any queries or require further information please contact me on telephone number **07784710667** or email: [pmuthinji@nhs.net](mailto:pmuthinji@nhs.net)

Yours Sincerely

Peter M Muthinji

Chief Investigator



# FORM UPR16

## Research Ethics Review Checklist

Please include this completed form as an appendix to your thesis (see the Postgraduate Research Student Handbook for more information)

<b>Postgraduate Research Student (PGRS) Information</b>		<b>Student ID:</b>	up642137	
<b>PGRS Name:</b>	Peter MUTHINJI			
<b>Department:</b>	SHSSW	<b>First Supervisor:</b>	Dr R ebecca STORES	
<b>Start Date:</b> (or progression date for Prof Doc students)	October 2013			
<b>Study Mode and Route:</b>	Part-time <input checked="" type="checkbox"/>	MPhil <input type="checkbox"/>	MD <input type="checkbox"/>	
	Full-time <input type="checkbox"/>	PhD <input type="checkbox"/>	Professional Doctorate <input checked="" type="checkbox"/>	

<b>Title of Thesis:</b>	A FEASIBILITY STUDY ASSESSING HOME VIDEO TELEMETRY POLYSOMNOGRAPHY (HVTP) AS A DIAGNOSTIC PROCEDURE FOR ADULT PATIENTS UNDERGOING INVESTIGATION FOR PARASOMNIAS
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<b>Thesis Word Count:</b>  (excluding ancillary data)	47,871
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If you are unsure about any of the following, please contact the local representative on your Faculty Ethics Committee for advice. Please note that it is your responsibility to follow the University's Ethics Policy and any relevant University, academic or professional guidelines in the conduct of your study

Although the Ethics Committee may have given your study a favourable opinion, the final responsibility for the ethical conduct of this work lies with the researcher(s).

### UKRIO Finished Research Checklist:

(If you would like to know more about the checklist, please see your Faculty or Departmental Ethics Committee rep or see the online version of the full checklist at: <http://www.ukrio.org/what-we-do/code-of-practice-for-research/>)

Have all of your research and findings been reported accurately, honestly and within a reasonable time frame?	YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>
Have all contributions to knowledge been acknowledged?	YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>
Have you complied with all agreements relating to intellectual property, publication and authorship?	YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>
Has your research data been retained in a secure and accessible form and will it remain so for the required duration?	YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>

Does your research comply with all legal, ethical, and contractual requirements?	YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>
--	--

<b>Candidate Statement:</b>		
I have considered the ethical dimensions of the above-named research project, and have successfully obtained the necessary ethical approval(s)		
<b>Ethical review number(s) from Faculty Ethics Committee (or from NRES/SCREC):</b>	NRES 14/LO/0457	
If you have <i>not</i> submitted your work for ethical review, and/or you have answered 'No' to one or more of questions a) to e), please explain below why this is so:		
<div style="background-color: #cccccc; height: 80px; width: 100%;"></div>		
<b>Signed (PGRS):</b>	<i>p mithinji</i>	<b>Date:</b> 10/05/2017