

ARTICLE

Investigating qualitative and quantitative validity of PSYCHLOPS: a novel Patient Reported Outcome Measure in a pilot study of primary care management of insomnia

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Abstract

Rationale, Aims and Objectives: PSYCHLOPS ('Psychological Outcome Profiles') is an idiographic patient-reported outcome measure that attempts to evaluate therapeutic progress. We aimed to assess the validity of PSYCHLOPS within a study of insomnia.

Methods: We investigated reliability, content, criterion and construct validity of PSYCHLOPS as part of a cluster randomized pilot study. Other measures used included the Pittsburgh Sleep Quality Index, Insomnia Severity Index, Beck Depression Inventory and sleep diaries. We administered PSYCHLOPS in a study seeking to educate primary care clinicians to deliver problem-focused and patient-centred therapy for insomnia with adults. The instrument was administered in intervention and control primary care sites. Sixty two participants measuring 5 and above on the PSQI were included in the study.

Results: The qualitative analysis showed expected responses for sleep problems. We found a positive correlation between PSYCHLOPS and ISI, but not between PSYCHLOPS and PSQI, suggesting partial criterion validity with regards to insomnia impact. We found a positive correlation between PSYCHLOPS and BDI supporting construct validity. However, these validity results rested on a number of assumptions insofar as patients who offered complex free text responses would have to rate their experiences at the beginning, midway and end of therapy respectively, in order for the tool to create a significant score. This would be difficult for patients to do, which undermines the tool's validity.

Conclusion: PSYCHLOPS demonstrated aspects of validity supporting further circumspect use and evaluation in practice. A combined qualitative and quantitative analysis added important dimensions to the assessment of validity for this tool. Nonetheless, idiographic measures like PSYCHLOPS provide a much needed patient voice to research and clinical outcome measures and are therefore important contributions to the development of person-centered medicine.

Keywords

BDI, CBT-I, CORE-OM, EQ-5D, ESS, HADS, IAPT, insomnia, ISI, patient voice, patient-reported outcome measures, person-centered medicine, primary care, PROMs, PSQI, PSYCHLOPS, qualitative validity, quantitative validity, sleep disturbances

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Introduction

Various instruments, including Patient Reported Outcome Measures (PROMs) [1], have been validated for assessing sleep related interventions in clinical and research settings [2,3], but none are idiographic, that is, patient generated. Due to the eclectic nature of sleep problems [4], standardized measures may contain redundant or irrelevant

items or miss salient aspects that are pertinent to a patient's sleep problems [5]. Psychological Outcome Profiles (PSYCHLOPS) is different from other PROMs in incorporating patients' own descriptions of their problems and meaning rather than pre-constructed statements developed from clinical diagnostic criteria [6].

Insomnia, the most commonly reported psychological complaint in Britain [7], is often persistent [8] and

associated with physical problems as well as psychological sequelae [9,10]. It is also linked to impaired quality of life, poorer social and occupational functioning, work-related accidents [5], increased healthcare utilization and costs [11,12].

Hypnotic drug therapy is widely used, despite concerns about safety and limited evidence of its effectiveness [13-15]. Cognitive behavioral therapy for insomnia (CBT-I) has been shown to be at least as effective as drugs short term and safer long term for the management of persistent or recurrent insomnia [16] and for co-morbid insomnia associated with anxiety, depression, pain or cancer [17]. Although programs, such as Improving Access to Psychological Therapies (IAPT) [18] now provide better access to non-pharmacological therapies for conditions such as anxiety and depression, cognitive behavioral therapy for insomnia (CBT-I) is still not widely used or available mainly because of the lack of trained providers [19].

PSYCHLOPS is primarily a mental health outcome measure and has not been used previously to assess sleep or sleep related-disorders. Whilst not originally developed for sleep problems, the PSYCHLOPS is a clinician administered tool, which has been shown to gather an array of narratives about mental health issues and which represents patients' voices within their personal and social contexts [6]. This personalized scoring questionnaire allows patients and professionals to evaluate progress before, during and following therapy by recording patients' self-defined problems within a Free Text box, their severity and duration [20]. The tool also includes a general wellbeing question. All Free Text responses are also measured by patients on a Likert scale [21].

The current study represents one part of a larger study, the broad goal of which was to improve treatment for people suffering with sleep problems by promoting a range of treatment options beyond just hypnotics which are not always the most appropriate course of action and carry the risk of side effects and addiction. We administered PSYCHLOPS as part of a pilot study to assess whether intervention training of general practice clinicians (GPs and nurses) including 'problem focused therapy,' had any bearing on patient outcomes. In doing so, we aimed to assess and provide validity evidence of PSYCHLOPS through the reporting of baseline data addressing qualitative and quantitative validity dialectically.

Methods

Situating the study

This study was part of a cluster randomized pilot study of a complex intervention [22]. Two primary care practices in Lincolnshire, UK were randomized to an educational intervention for problem focused therapy, which included a consultation approach to patients' sleep problems and insomnia comprising of careful assessment including assessment of secondary causes, sleep diaries and use of modified Cognitive Behavior Therapy for Insomnia (CBT-

I) in the consultation. A control group at 2 different primary care practices in Lincolnshire, UK offered treatment as usual and were given sleep hygiene advice. A practice nurse administered PSYCHLOPS with other predetermined measures: the Pittsburgh Sleep Quality Index (PSQI) [3], Insomnia Severity Index (ISI) [2] and sleep diaries to assess sleep quality; Epworth Sleepiness Scale (ESS) for daytime sleepiness [23]; the Beck Depression Inventory (BDI) [24] and quality of life using EuroQoL EQ-5D [25] to adult patients.

At the start of the therapy, data were collected using PSYCHLOPS that represent qualitative responses and scores on the 2 most important problems in respondents' lives during the past week and any function that has been impaired due to these problems. During therapy, the initial problems identified by the patient on PSYCHLOPS are restated on a new form and patients are asked to rate these problems and functional domains again. There is an additional question at this stage, allowing patients to further identify and score a problem that may have surfaced during therapy. The end of treatment sheet is offered to the patient, with the same problems and functioning problem initially identified, in order to generate a final score. The quantitative data was analyzed separately from the qualitative data.

We were interested in content validity (nature of response to items), internal validity (internal consistency or reliability), criterion validity (strength of relationship with a related variable) and construct validity (strength of relationship with an underlying variable) [26]. Quantitative data were analyzed using SPSS version 15. Qualitative data were analyzed using MAXQDA. Free-text data were open coded using as many codes as were deemed necessary to identify the properties and dimensions offered by the participants. Each case was open coded by 2 authors (ZD and HW) separately and then standardized following a number of coding sessions [6,27,28]. This approach enabled us to create codes that were linguistically the same or very similar to the patients' responses to evaluate the tool idiographically. We wanted to identify phenomenologically important aspects of patients' experiences and functioning that they were associating with their sleep problems.

Participants

In total, 62 participants, 34 women and 28 men all of whom measured 5 and above on the PSQI scale were administered PSYCHLOPS. Eighty-seven per cent of participants reported that they had had sleep problems for over 1 year and 43% said that they had lasted for more than 5 years. Sixty responses (33 women and 27 men) were used for the qualitative analysis (2 cases did not offer any free-text responses). In addition, 1 case did not answer question 1; 8 different cases did not answer question 2; 3 different cases did not answer question 3 & 1 different case answered neither question 1 nor 2.

The data from these cases were included, but coded as 'unanswered,' so that we could determine if there were any similarities in relation to the types of data offered in the

adjacent questions. There did not appear to be any discernable patterns to the unanswered questions.

We were granted ethics approval by Derbyshire Research Ethics Committee, UK. REC reference number: 08/H0401/89. Informed consent was granted by all participants.

Results

Qualitative Content validity

Content validity can have a non-statistical basis if it involves “the systematic examination of the test content to determine whether it covers a representative sample of the behavior domain to be measured” [29]. We examined content validity by investigating whether and to what extent the free-text responses related to clinical consultations for sleep problems including sleep problems themselves, their causes or consequences. In order to achieve this, the responses for question 1 were ‘open coded’ [28] into 26 codes and, for question 2, 30 codes. These codes were systematically organized, which generated 4 themes: sleep-related; psychological; sociological and physical. The third question was concerned with functioning and yielded 23 codes, which also corresponded to the 4 themes.

Insomnia, sleep disturbance and related responses

The majority of responses to question 1 did relate directly to sleep disturbances at night or tiredness. For example, “not continuous sleep” (Case 7), “sleeping” (Case 24) all seemed to relate well to the functioning problems stated. Items, such as “motivate myself” (Case 7), “concentrate” (Case 24), “function/concentrating at work not 100%” (Case 29) and “socialising” (Case 9) were some of the statements. Although patients identified that sleep, tiredness and associated sleep disturbances were their main concern, they rarely expanded on this and their responses were kept to either single-word responses or at most a small number of words, such as “not being able to sleep” (Case 3), “Chronic Insomnia” (Case 19) or “disturbed sleep (when not taking tablets)” (Case 37).

Sociological and psychological responses

Sociological and psychological responses were often offered in more interdependent ways. Sociological data consisted of family concerns, such as bereavement, caring and relationship responsibilities, work related concerns, financial worries, isolation and loneliness and body image, all of which were coupled with emotional concerns, such as motivation, anxiety and stress. Stand-alone psychological responses often used diagnostic terms such as anxiety, stress and coping. However, a number of responses included sentiments such as, “live a normal life” (Case 47), “hard to feel good, feel less capable, not like me

at all” (Case 61) and “being short tempered with children” (Case 24).

Physical responses

A small number of patients offered data about a physical condition that seemed to correspond well to their sleep problem and functioning problem. On these occasions, the physical problem would relate to some form of pain that disrupted their sleep. For example “Back problem” was associated with “not able to take long walks” (Case 38) and in other cases relating to functioning, they “[h]ad to stop gardening and hoovering and carrying heavy shopping bags” (Case 17). Nonetheless, it was difficult to ascertain if these patients were referring to their inability to do daily chores because of fatigue or because of the physiological inability or because of the pain.

Complex and inter-related responses

There were a number of responses that had to be qualitatively coded in a variety of domains due to the complexity of response. For example, “worries about my wife after heart by-pass; worried about my job and health problems; worries over my private life and my family” (Case 56) were coded as family, illness, other’s illness and work. The secondary and functioning questions in these cases were also more complex. Case 21 answered question 1 with “[g]oing back to work and fulfilling my career” with a secondary problem defined as “[m]y relationship and how things over past 18 months have changed it [sleep?]” followed by the functioning response, which was “[k]now how to begin to be myself again.” Interestingly, one participant stated: “I have no problems that I am aware of” in response to questions 1 and 2 accompanied with “control the amount of pain from arthritis” (Case 14) as the functioning problem.

Quantitative validity

Table 1 shows the overall response rates and summary statistics of instruments used in the trial. PSYCHLOPS had the lowest completion rate (i.e., completion of all components for baseline and follow-up). The PSYCHLOPS, PSQI and ISI had the lowest relative variation, as measured by the coefficient of variation (0.27, 0.27 and 0.31 respectively) which was also lower than the ESS (0.75) and BDI (0.58) instruments.

There did not appear to be a relationship between sex or age and the scores generated by PSYCHLOPS.

Table 2 shows the relative frequencies of the Likert-scaled severity reported by respondents for the primary and secondary identified problems, difficulty performing a named task and self-rated wellbeing. Having named one thing that was hard to do because of the (named) problems, respondents were asked, “How hard has it been to do this thing over the last week?” Scores were skewed towards “Very Hard”; which was not surprising, since respondents were instructed already to select a task that was hard to do.

Despite this, 25% of respondents scored difficulty at the mid-point or below.

Table 1 Summary statistics of the PSYCHLOPS, PSQI, ISI, ESSS and BDI instruments

Score	N	Mean	Standard deviation	Minimum	Maximum
PSYCHLOPS	47	18.04	4.96	7	28
PSQI	62	12.95	3.47	6	21
ISI	60	16.97	5.25	4	26
ESS	59	7.08	5.31	0	21
BDI	60	13.80	8.00	0	30

PSQI: Pittsburgh Sleep Quality Index; ISI: Insomnia Severity Index; ESI: Epworth Sleepiness Scale (ESS); Beck Depression Inventory (BDI).

Table 2 Frequencies of PSYCHLOPS scores for problems 1 and 2, task difficulty and wellbeing

	How has (problem 1) affected you?	How has (problem 2) affected you?	Difficulty performing a named task	Self rated feeling of well-being
Not at all/very good (0)	4 (6.7)*	6 (11.5)	5 (8.9)	7 (11.7)
1	2 (3.3)	2 (3.9)	3 (5.4)	8 (13.3)
2	7 (11.7)	7 (13.5)	8 (14.3)	11 (18.3)
3	21 (35.0)	20 (38.5)	14 (25.0)	17 (28.3)
4	13 (21.7)	9 (17.3)	8 (14.3)	13 (21.7)
Very much/hard/bad (5)	13 (21.7)	8 (15.4)	18 (32.1)	4 (6.67)

* N (%)

Correlation between severity in the 2 problems, measured by Kendall’s tau [30] was 0.58 ($p < 0.001$). Difficulty felt performing the named task and the severity of problems 1 and 2, were moderately correlated with Kendall’s tau 0.58 ($p < 0.001$) and 0.48 ($p < 0.001$) respectively. Respondents were asked about wellbeing, “How have you felt in yourself this week?” Kendall’s tau between this self-rated feeling and the severity of problems 1 and 2 was 0.62 ($p < 0.001$) and 0.46 ($p < 0.001$) respectively. Kendall’s tau between self-rated feeling and the difficulty felt performing the named task was 0.58 ($p < 0.001$).

The findings suggested a moderately strong correlation between the severity of identified problems, the difficulty in performing an identified (and presumably related or relevant) task and self-rated feelings. The responses showed that the primary problem identified was correlated more strongly than the secondary problem with performance of the difficult task and how the respondent felt.

Criterion validity

Criterion or convergent, validity, was established by assessing the degree to which PSYCHLOPS correlated

with other measures when this was theoretically expected [31], that is, PSQI and ISI. PSYCHLOPS did not correlate with PSQI (Kendall’s tau = 0.13, $p = 0.24$), but there was moderate correlation with ISI (Kendall’s tau = 0.47, $p < 0.001$). Correlation between ISI and PSQI scores was also low (Kendall’s tau = 0.30, $p = 0.001$). However, the trial was not powered to establish such a correlation; the lack of correlation comparing PSYCHLOPS and PSQI could be a matter of sample size only. Both Figure 1 and Figure 2 illustrate non-scored (missing) data for several of the ISI and PSQI scores.

Figure 1 Relationship between PSYCHLOPS and the PSQI

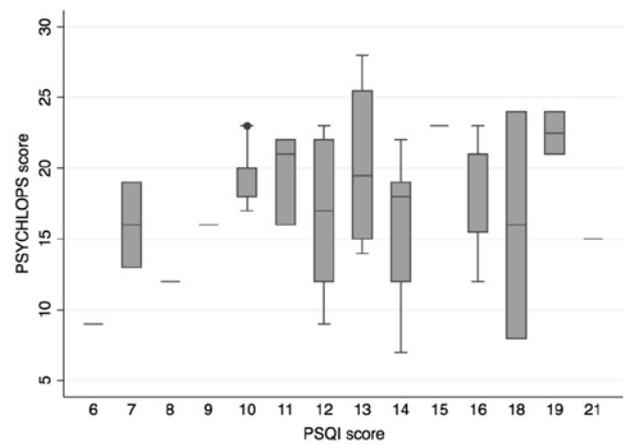
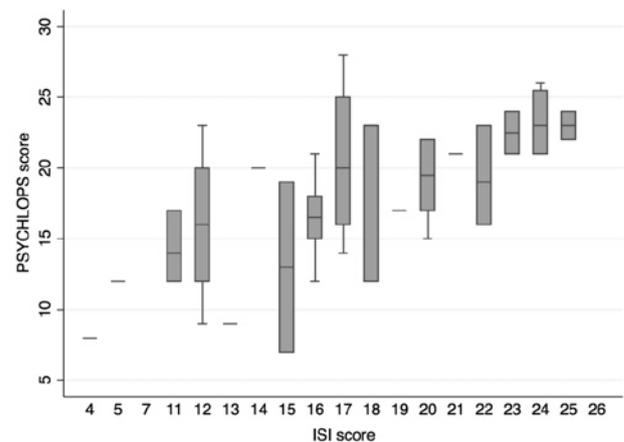


Figure 2 Relationship between PSYCHLOPS and ISI scores



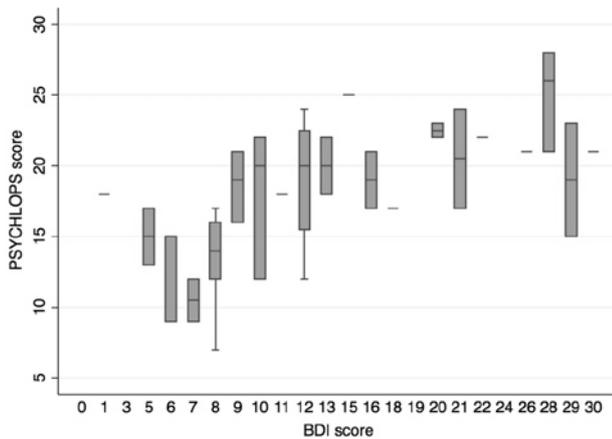
Construct validity

Construct validity is assessed according to how well an operationalized construct - in this case, a test/instrument developed from theory, truly measures that which the theory predicts. For testing construct validity we compared PSYCHLOPS with the BDI because sleep problems are often co-morbid with anxiety and depression [32].

PSYCHLOPS and BDI were positively and statistically significantly correlated (Kendall’s tau = 0.47, $p < 0.001$). Moreover, BDI scores were also positively correlated with PSQI and ISI scores: Kendall’s tau 0.31

($p=0.001$) and 0.41 ($p<0.001$), respectively. Therefore PSYCHLOPS demonstrated moderate evidence of criterion and construct validity.

Figure 3 Relationship between PSYCHLOPS and BDI



Discussion

Qualitative responses usually related to the eclectic array of sleep problems and their (assumed) causes or consequences. In terms of quantitative validity, the correlations measured exceeded critical correlation coefficient thresholds for significance at these samples sizes, a necessary hurdle for validity. However, few of the correlations were strong and none for either criterion or construct validity exceeded 0.5. On this basis, we were able cautiously to validate the tool both quantitatively and qualitatively and found evidence that PSYCHLOPS could be used in sleep research and provides a patient-centered tool for clinical practice. There have been 2 published validation studies involving PSYCHLOPS in which the authors of the tool assessed criterion validity against the psychometric tools, Clinical Outcomes in Routine Evaluation - Outcome Measure (CORE-OM), which was constructed by a group of practitioners to assess patients' psychological distress [33] and the Hospital Anxiety and Depression Scale (HADS) [34,35]. Completion rates were 47% and 34% respectively and evidence was shown of convergent, concurrent and construct validity in these studies. These were quantitative validations, seeking accuracy, relevance and reliability of the tool. So far, the existing research has been based around the validity of PSYCHLOPS primarily as a mental health outcome measure and has not been used to assess sleep or sleep related-disorders. Since sleep problems and insomnia can occur as a result of varied causes, it is essential for clinicians to be able to evaluate the differential sleep problems to allow successful treatment planning [36].

Insights into validity testing

Previous studies have sought to validate PSYCHLOPS quantitatively [34,35], independently from qualitative evaluations [6,20]. Conflicts between positivist and

interpretive research philosophies arguably lead to incompatible formulations of validity and might pose a problem here [37]. Quantitative researchers would typically use statistical methods to compare a new instrument with existing measures [38]. It is obvious that qualitative tools cannot be validated using the same criteria [37,39,40]. Nonetheless, in the literature, there are broadly 3 views pointing to how qualitative studies can be validated. There are those who wish qualitative research to be judged according to the same criteria as quantitative research, those who believe that a different set of criteria are required and those who question the appropriateness of any predetermined criteria (as is the case for quantitative validity) [41]. We took the view that the concept of 'validity' could be used here for both approaches, since qualifying explanations are offered as to the philosophical and epistemological underpinning of the evaluation of validity that is discussed. We would argue that the evaluation of a tool, which combines qualitative and quantitative elements needs to integrate both epistemological approaches [38], because it will clarify the ways in which PSYCHLOPS may be utilized for sleep problem-focused therapy.

There were no normative reference points for PSYCHLOPS, preventing comparison of patients' responses at baseline. The use of free-text boxes allowed infinite ways of responding, creating problems for both qualitative and quantitative validity. Although the free-text box allowed space for a detailed explanation of an associated problem it was rarely used to offer in-depth insights into patients' sleep problems. Often, a narrow range of words was used by patients and the brevity of response representing a brief summary of patient's experience limited the extent to which the narratives could be analyzed as one would in a qualitative study, but simplified the quantitative analysis.

Opposite to brevity, length may also cause problems for the validity of the tool, particularly in measuring patients' interconnected problem(s) aggregately at the start, midway and end of the evaluation. To do so would have to rest on a number of assumptions. Firstly, analysis would have to assume that the patient pinpointed exactly what their foremost, secondary and functioning problems were prior to therapy and that these factors were causal and static in relation to their sleep problems. Secondly, the accuracy of patients' evaluations and measurements when multiple factors are associated with the sleep problem is assumed. As we saw with case 56, the respondent would have to measure "Worries about my wife after heart bypass. Worried about my job and health problems. Worries over my private life and my family," then remember how s/he felt and was experiencing this complexity at the midway and end point in order to offer any meaningful measurement. This, we would argue, is very difficult for respondents. Moreover, measurements at the midway and end point may have little to do with any therapy that is being offered and the tool could retrieve a better or worse score because of confounding factors, such as his/her spouse getting better or worse, a new manager at work who is more accommodating and so on.

According to some, patient-generated measures are instruments less well designed to measure both change over time ('evaluative') and discrimination ('discriminative') between 2 groups of patients [35]. According to the author of the tool, 'maximising the evaluative attributes is likely to be achieved at the cost of diminishing the discriminative attributes. In relation to this, evaluative instruments are more likely to detect real clinical change but tend to have lower reliability' [35]. This might undermine the idiographic nature of PSYCHLOPS that is claimed to be a strength [20]. Too little data may not allow meaningful phenomenological analysis whereas too much complexity could reduce reliability. PSYCHLOPS might be better administered after the first session of therapy, when various avenues have been explored and decisions made on which to focus on in the therapeutic sessions, since initial problems and related functioning are carried through at each stage and need to be consistent for the tool to work as it is intended to.

The administration of the questionnaire may influence how patients complete it. Validity in a qualitative sense could depend on consistency of data retrieval through the research process. We were able to infer from the (missing) data that PSYCHLOPS was understood by patients and completed unaided or 'interfered' with by a researcher. Responses were in line with responses that would generally be understood as contributing to sleep problems or insomnia in general practice (Author, personal communication). Qualitative validity is concerned with descriptive, interpretive and theoretical validity as well as the accuracy and authenticity of data [41,42] and how these fit with existing theoretical models or inform new theory. Since thematic categories constructed from the data included psychological, physical and sociological experiences, which were different, but related to sleep and insomnia problems, we found this to be a positive aspect of the tool, but whether these can be accurately measured by PSYCHLOPS is debatable.

Adding value to sleep therapy

Researchers have argued that until healthcare professionals are able to use and evaluate PROMs that capture issues of importance to patients their potential will remain unknown [43]. Our findings offer a better understanding of PSYCHLOPS, how it facilitates inductive responses about patients' experiences and a more person-centered measure of interconnected problems.

Strengths and limitations

We used PSYCHLOPS in the context of a pilot trial for management of insomnia. Data were collected in a standard way and were analyzed combining quantitative and qualitative approaches. Although the size of sample may not have been sufficient to show strong correlations between some measures and randomization in a fully powered study would equalize confounders across intervention and control groups, it was unlikely that

positive results occurred by chance. However, it was also important that the correlation should not be perfect since then PSYCHLOPS would duplicate information from the ISI and PSQI tools, rather than provide a better tool to help clinicians to improve focus on salient concerns of patients.

Conclusion

PSYCHLOPS demonstrated qualified qualitative and quantitative validity and, because of its patient-centered approach, has potential to provide additional information to other measures in clinical practice and research settings. The arguments for meaningful validity, however, need to take into account the context in which the instrument is administered and potential conflicts between qualitative and quantitative notions of validity. Nonetheless, idiographic measures like PSYCHLOPS, which incorporate patients' own descriptions of their problems and meanings, provide a much needed patient voice to research outcome measures. However, future evaluations of PSYCHLOPS for sleep-related problems and insomnia must consider whether the measure is a reflection of a patients' condition or problems in order to arrive at a significant therapeutic assessment and outcome. Before this measure can be routinely used in sleep research it needs to be tested in diverse populations incorporating differences in language, age, disease status and educational level.

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References

- [1] Devine, E.B., Hakim, Z. & Green, J. (2005). A systematic review of patient-reported outcome instruments measuring sleep dysfunction in adults. *Pharmacoeconomics* 23, 889-912.
- [2] Bastien, C.H., Vallieres, A. & Morin, C.M. (2001). Validation of the Insomnia Severity Index as an outcome measure for insomnia research. *Sleep Medicine* 2 (4) 297-307.
- [3] Buysse, D.J., Reynolds III, C.F., Monk, T.H., Berman, S.R. & Kupfer, D.J. (1989). The Pittsburgh sleep quality index: A new instrument for psychiatric practice and research. *Psychiatry Research* 28 (2) 193-213.
- [4] Williams, S.J. (2002). Sleep and Health: Sociological reflections on the dormant society. *Health* 6 (2) 173-200.
- [5] Kyle, S.D., Espie, C.A. & Morgan, K. (2010). "... Not Just a Minor Thing, It Is Something Major, Which Stops You From Functioning Daily": Quality of Life and

- Daytime Functioning in Insomnia. *Behavioral Sleep Medicine* 8, 123-140.
- [6] Robinson, S.I., Ashworth, M., Shepherd, M. & Evans, C. (2006). In their own words: a narrative-based classification of clients' problems on an idiographic outcome measure for talking therapy in primary care. *Primary Care Mental Health* 4, 165-173.
- [7] Singleton, N., Bumpstead, R., O'Brien, M., Lee, A. & Meltzer, H. (2001). Psychiatric morbidity among adults living in private households. London: The Stationary Office.
- [8] Morphy, H., Dunn, K.M., Lewis, M., Boardman, H.F. & Croft, P.R. (2007). Epidemiology of Insomnia: a Longitudinal Study in a UK Population. *Sleep* 30 (3) 274-280.
- [9] Taylor, D.J., Lichstein, K.L., Weinstock, J., Sanford, S. & Temple, J.R. (2007). A Pilot Study of Cognitive-Behavioral Therapy of Insomnia in People with Mild Depression. *Behavior Therapy* 38 (1) 49-57.
- [10] Ford, D.E. & Kamerow, D.B. (1989). Epidemiological study of sleep disturbances and psychiatric disturbances. *Journal of the American Medical Association* 5 (262) 1479-1484.
- [11] Hayward, R., Jordan, K.P. & Croft, P. (2010). Healthcare use in adults with insomnia: a longitudinal study. *British Journal of General Practice* 60, 334-340.
- [12] Ozminkowski, R.J., Wang, S. & Walsh, J.K. (2007). The direct and indirect costs of untreated insomnia in adults in the United States. *Sleep* 30, 263-273.
- [13] Siriwardena, A.N., Qureshi, M.Z., Dyas, J.V., Middleton, H. & Ørner, R. (2008). Magic bullets for insomnia? Patients' use and experiences of newer (Z drugs) versus older (benzodiazepine) hypnotics for sleep problems in primary care. *British Journal of General Practice* 58, 417-422.
- [14] Glass, J., Lanctôt, K.L., Herrmann, N., Sproule, B.A. & Busto, U.E. (2005). Sedative hypnotics in older people with insomnia: meta-analysis of risks and benefits. *British Medical Journal* 331 (7526) 1169.
- [15] Buscemi, N., Vandermeer, B., Friesen, C., Bialy, L., Tubman, M., Ospina, M., Klassen, T. & Witmans, M. (2007). The Efficacy and Safety of Drug Treatments for Chronic Insomnia in Adults: A Meta-analysis of RCTs. *Journal of General Internal Medicine* 22 (9) 1335-1350.
- [16] Morin, C.M., Bootzin, R.R., Buysse, D.J., Edinger, J.D., Espie, C.A. & Lichstein, K.L. (2006). Psychological and behavioral treatment of insomnia: update of the recent evidence (1998-2004). *Sleep* 29, 1398-1414.
- [17] Smith, M.T., Huang, M.I. & Manber, R. (2005). Cognitive behavior therapy for chronic insomnia occurring within the context of medical and psychiatric disorders. *Clinical Psychology Review* 25 (5) 559-592.
- [18] Department of Health. (2008). Improving Access to Psychological Therapies (IAPT): Commissioning Toolkit. London: Department of Health.
- [19] McKinstry, B., Wilson, P. & Espie, C. (2008). Non-pharmacological management of chronic insomnia in primary care. *British Journal of General Practice* 58 (547) 79-80.
- [20] Ashworth, M., Robinson, S.I., Evans, C., Shepherd, M., Conolly, A. & Rowlands, G. (2007). What does and idiographic measure (PSYCHLOPS) tell us about the spectrum of psychological issues and scores on a nomothetic measure (CORE-OM)? *Primary Care and Community Psychiatry* 12 (1) 7-16.
- [21] Czachowska, S., Seed, P., Schofield, P. & Ashworth, M. (Unpublished) Measuring Psychological Change During Brief Cognitive Behaviour Therapy in Primary Care: A Polish Study Using 'PSYCHLOPS'.
- [22] Siriwardena, A.N., Apekey, T., Tilling, M., Harrison, A., Dyas, J., Middleton, H., Ørner, R., Sach, T., Dewey, M. & Qureshi, Z. (2009). Effectiveness and cost-effectiveness of an educational intervention for practice teams to deliver problem focused therapy for insomnia: rationale and design of a pilot cluster randomised trial. *BMC Family Practice* 10 (1) 9.
- [23] Johns, M.W. (1991). A new method for measuring daytime sleepiness: the Epworth sleepiness scale. *Sleep* 14 (6) 540-545.
- [24] Salkind, M.R. (1969). Beck depression inventory in general practice. *Journal of the Royal College of General Practitioners* 18 (88) 267-271.
- [25] Kind, P., Hardman, G. & Macran, S. (1999). UK population norms for EQ-5D. York: University of York, Centre for Health Economics, (CHE discussion paper).
- [26] Reis, H.T. & Judd, C.M. (2000). Handbook of research methods in social and personality psychology. New York: Cambridge University Press.
- [27] Berg, B.L. (1989). Qualitative research methods for the social sciences. New York: Allyn and Bacon.
- [28] Strauss, A. & Corbin, J. (1990). Basics of Qualitative Research: Grounded Theory Procedures and Techniques. Newbury Park: Sage.
- [29] Anastasi, A. & Urbina, S. (1997). Psychological testing, 7th edn. Upper Saddle River: Prentice Hall.
- [30] Kendall, M.G. (1938). A new measure of rank correlation. *Biometrika* 30, 81-93.
- [31] Streiner, D.L. & Norman, G.R. (2008). Health measurement scales: a practical guide to their development and use, 4th edn. Oxford: Oxford University Press.
- [32] Staner, L. (2010). Comorbidity of insomnia and depression. *Sleep Medicine Reviews* 14 (1) 35-46.
- [33] Barkham, M., Mellor-Clark, J., Connell, J. & Cahill, J. (2006). A core approach to practice-based evidence: A brief history of the origins and applications of the CORE-OM and CORE System. *Counselling and Psychotherapy Research* 6 (1) 3-15.
- [34] Ashworth, M., Evans, C. & Clement, S. (2009). Measuring psychological outcomes after cognitive behaviour therapy in primary care: a comparison between a new patient-generated measure "PSYCHLOPS" (Psychological Outcome Profiles) and "HADS" (Hospital Anxiety and Depression Scale). *Journal of Mental Health* 18 (2) 169-177.
- [35] Ashworth, M., Robinson, S.I., Godfrey, E., Shepherd, M., Evans, C., Seed, P., Parmentier, H. & Tylee, A. (2005). Measuring mental health outcomes in primary care: the psychometric properties of a new patient-generated outcome measure, 'PSYCHLOPS' (psychological outcome profiles). *Primary Care Mental Health* 3 (4) 261-270.
- [36] Chesson, A., Hartse, K., Anderson, W.M., Davila, D., Johnson, S., Littner, M., Wise, M. & Rafecas, J. (2000).

Practice parameters for evaluation of chronic insomnia. *Sleep* 23, 1-5.

[37] Hammersley, M. (1987). Some Notes on the Terms 'Validity' and 'Reliability'. *British Educational Research Journal* 13 (1) 73-82.

[38] Whittemore, R., Chase, S.K. & Mandle, C.L. (2001). Validity in Qualitative Research. *Qualitative Health Research* 11 (4) 522-537.

[39] Wainwright, D. (1997). Can Sociological Research Be Qualitative, Critical and Valid? *The Qualitative Report* 3 (2). Available from: <http://www.nova.edu/ssw/QR/QR3-2/wain.html>.

[40] Pyett, P.M. (2003). Validation of Qualitative Research in the "Real World". *Qualitative Health Research* 13 (8) 1170-1179.

[41] Rolfe, G. (2006). Validity, trustworthiness, and rigour: quality and the idea of qualitative research. *Journal of Advanced Nursing* 53 (3) 304-310.

[42] Hannes, K., Lockwood, C. & Pearson, A. (2010). A Comparative Analysis of Three Online Appraisal Instruments' Ability to Assess Validity in Qualitative Research. *Qualitative Health Research* 20 (12) 1736-1743.

[43] Marshall, S., Haywood, K. & Fitzpatrick, R. (2006). Impact of patient-reported outcome measures on routine practice: a structured review. *Journal of Evaluation in Clinical Practice* 12 (5) 559-568.