Mémoire de Bachelor / Bachelorarbeit

Content analyses of a pain diary

A Qualitative and Quantitative Investigation via Cognitive Interviewing and Discriminant Content Analysis

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Abstract

Background: Pain is a growing public health problem that affects more than twenty percent of the population world-wide. Therefore, the investigation of pain is not only beneficial, but also necessary. However, a solid assessment requires valid instruments as the derived data build the basis for further conclusions. Since pain questionnaires show certain shortcomings in depicting pain adequately, another tool, a pain diary, will be introduced and examined. The aim of the study was to investigate the content validity of the PainDiary.

Methods: Discriminant content validity (DCV) and cognitive interviews (CI) were carried out with people experiencing no pain, acute pain and chronic pain. DCV: One-sample t-tests were run to display whether each item measures the targeted construct. CI: The interviews were conducted, and interview transcripts were analyzed on a question-by-question basis to identify any major problems in understanding and using the PainDiary.

Results: The DCV revealed 15 pure items reflecting only one construct and 11 mixed items which indicated an overlap in depicted constructs. The CI analysis demonstrated that participants had good comprehension and showed rational decision-making processes in choosing their responses. However, it pointed out a lack of clarity for a certain number of items which may need some revision.

Conclusions: The content validity and acceptability of the Pain Diary has been investigated in a quantitative and qualitative approach. This analysis provides a reliable data resource which allows the improvement and modification of certain items. The broader application of the PainDiary should be evaluated and may benefit patients and researchers to study pain.

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1. Introduction

1.1 Pain

Pain can be defined as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage" (Bonica, 1979). This definition includes both, the sensory and the emotional aspects of suffering and states no necessity for a present tissue damage. Pain of any kind can have a huge impact on one's life quality. Pain has been described as "the major source of suffering" (Treede et al., 2015), which stresses its importance. Evidence has shown that it can turn an individual's well-being into a severe vulnerable state which leads to the following main outcomes: impairment, activity limitations and participation restrictions (Dixon, Pollard, & Johnston, 2007). However, the definition of pain is quite broad. Therefore, a taxonomy serves to define the different types on the basis of certain criteria.

The classification of pain can be realized in a number of different ways, i.e. by a categorical approach (i.e. acute, acute recurrent, chronic, chronic progressive, and laboratory-induced), by diagnosis and its underlying mechanisms (i.e. back pain), by severity (i.e. "mild", "moderate", "severe") or by age of the individual (i.e. infant, adolescent, adult). However, so far, "no single system for classifying pain patients has been universally accepted by clinicians or researchers" (Turk & Melzack, 2001).

Building upon the classification by duration, "a distinction is made between acute (<3 months) and chronic (>3month) pain" (Wager & Zernikow, 2014). This form of classification provides the advantage of precision and operationalization: "chronic pain is defined as persistent or recurrent pain lasting longer than 3 months" (Treede et al., 2015).

1.1.1 Chronic pain.

Especially chronic pain has been recognized as a separate phenomenon compared to acute pain (Merskey & Bogduk, 1994). It causes lasting consequences for both the individual and the society. In other words, it affects the patient's physical, psychosocial and social well-being (Fine, 2011; Gerrits et al., 2012) and further results in an enormous amount in healthcare costs (Dagenais, Caro, & Haldeman, 2008). Several scholars have suggested that the main causes for the establishment and maintenance of chronic pain are related to psychological and social factors (Treede et al., 2015). Psychological aspects influencing chronic pain can be anxiety or depression (Zernikow et al., 2012). In particular, the interaction of emotions and cognitive processes, e.g., pain appraisals and beliefs, have been suggested to play a central role in the development and maintenance of chronic pain (Wager & Zernikow, 2014). In addition, a number of social aspects affect pain. These may for example be related to the behavior of peers or parents. In this context, some studies have shown that the parent's behavior can affect the child's pain perception. In particularly it was found that parents' tendency of pain catastrophizing is associated with a higher focusing of the child on its pain (Goubert, Vervoort, Ruddere, & Crombez, 2012).

1.1.2 Prevalence of chronic pain.

The high prevalence of chronic pain illustrates the necessity for an improved pain management. The International Association on the Study of Pain states that one in five people are diagnosed with moderate to severe chronic pain world-wide (Treede et al., 2015). Comparable high numbers have been assessed in Europe, where a key study states that "chronic pain of moderate to severe intensity occurs in 19% of adult Europeans" (Breivik, Collett, Ventafridda, Cohen, & Gallacher, 2006).

To summarize, chronic pain results in a significant burden for the health care system and needs to be given considerable attention. Most types of chronic pain are insufficiently

understood, and are lacking successful management (Turk & Melzack, 2001). Ultimately, this high prevalence and high levels of burden for the person, his environment and the society stress the need for further investigation of pain.

1.2 Pain Assessment

The basis for adequate research and treatment of pain requires a valid and reliable assessment of pain and its consequences. Indeed, reliable pain assessment is important to detect pain mechanisms and to develop methods for controlling pain (Turk & Melzack, 2001). Although some instruments are available, there is a need for valid instruments to assess pain, its antecedents and its outcomes. An improvement of pain measurement is imperative because it enables clear communication among clinicians, researchers and patients. Notably, physiological variables, such as heart rate, do not correlate strongly enough with pain to define them as a marker (Tousignant-Laflamme, Rainville, & Marchand, 2005), therefore we don't have an object measure of pain. That means we use a subjective to assess pain the person is asked to describe their pain experience via self-report (Jensen & Karoly, 2014). Indeed, this underscores the need for reliable self-report outcomes.

1.2.1 Self-reported data.

In order to provide proper self-report measures (e.g., questionnaires) to assess pain, following assumptions are required: (a) the respondent understands the intention of the questions, (b) the respondent recalls information accurately and, (c) the respondent formulates answers accurately (Stone, 2000). To address these conditions, a cognitive approach has been suggested to improve the quality of self-report measures (Jobe, 2010). Self-reported questions generally request behavioral information, but also opinion and subjective responses. For example, assessing pain intensity involves a subjective perceived feeling which will be transformed into numerical quantitative estimates (Jensen & Karoly, 2014). Due to the multifaceted and subjective nature of pain, these measurements are prone

to weaknesses in its precision (Younger, McCue, & Mackey, 2009). Studies have shown that qualitative investigation which include a cognitive approach (cognitive interviews) improve the quality of self-reports (Jobe, 2010).

1.2.2 Pain questionnaires.

First of all, in order to decide on tools that capture pain outcomes best , it has to be determined what outcome is relevant for the researcher or clinician (Younger et al., 2009). The most common instruments to measure pain are questionnaires. Generally, they provide a reflection of pain intensity (Jensen & Karoly, 2014). However, it must be pointed out that this approach is limited in displaying the variability during the course of the pain-experience. Indeed, pain questionnaires often report back on pain outcomes during the last 2 weeks or even during the last month. The Royal College of Surgeons and Royal College of Anaesthetists (1990) outlines that „pain must be assessed and documented on a regular basis“ (Windsor, Glynn, & Mason, 1996), which already implies the insufficient frequency of assessing pain by questionnaires. The majority of measures assess commonly a period of seven days (Cella et al., 2010), this is useful for several clinical settings, but cannot reflect any precise fluctuations within a day. Additionally, reflecting on pain experienced during a longer period of time is prone to recall bias which again interferes with the precision of the outcome (Redelmeier & Kahneman, 1996). Moreover, the patient-centered approach fails in most standard pain questionnaires, because of its lack in picturing the variety of different facets of pain, as for example, pain intensity, pain quality, or pain interference.

In conclusion, available questionnaires provide a good base for data collection by addressing some clinical relevant outcomes. Yet, they do not meet all the above-mentioned considerations. Therefore, the need has been expressed for measures that better capture fluctuations of pain outcomes and are less susceptible to memory biases.

1.2.3 Pain diary methodology.

To overcome some of the above-mentioned shortcomings, which are inherent to questionnaires, researchers have proposed to use pain diaries. Diaries are an established method in psychological research. To our knowledge the first diary study in a systematic form was conducted in 1977 by Csikszentmihalyi (Iida, Shrout, Laurenceau, & Bolger, 2012). They structured reporting forms and response intervals which is called ecological momentary assessment (EMA). Diaries are self-report measures reporting on a short time window (e.g., the past day, just before the beep-sound). Previous studies have shown that diary assessment provides a considerable contribution to the study of pain (Gendreau, Hufford, & Stone, 2003; Peters et al., 2000). Compared to other tools, pain diaries have shown the same sensitivity as in-clinic pain intensity measures, like questionnaires (Trudeau et al., 2015). Moreover, these diaries provide an improvement on three main points: reduction of recall bias, depiction of pain fluctuation of pain-related measures and a patient- centered approach. Particularly, the electronic pain diary has proven to be more responsive than paper diaries. The results have shown that the electronic assessment did not only reveal pain scores did not only have a higher response rate than paper diaries but also that the digital approach was described as being more convenient and user-friendly (Trudeau et al., 2015).

1.2.3.1 Advantages of pain diaries.

The use of pain diary methodology has several advantages. First, retrospective pain assessment (i.e. questionnaires) is based on memory retrieval which can be highly biased by the patient's ability to remember (Broderick, Schneider, Schwartz, & Stone, 2010). In line with these findings, Redelmeier and Kahneman (1996) agree that summary pain reports, like questionnaires, are disproportionately biased by peak pain and pain experience that occurs shortly before recall. Hence, evidence has shown that retrospective questionnaires cause recall errors, whereas prospective diaries reduce this bias (Van Den Brink, Bandell-Hoekstra,

& Huijer Abu-Saad, 2001). For this reason, pain diaries provide the advantage to assess pain without or at least with less recall bias. Gendreau, Hufford and Stone (2003) have shown that diaries greatly minimize recall bias. This makes a real difference in the accuracy of the data collection.

Secondly, Kumar and Elavarasi (2016) state that „The location, the time course, quality, and tenderness provide important clues for diagnosis, which are used as one of the best hints to evaluate the response to treatment", therefore, a in real time effective diary assessment provides ideal opportunities for an improved measurement of these parameters. In effect, diaries capture pain accurate in cases where daily or multiple daily pain scores are desired (Trudeau et al., 2015). By gathering current states outside the lab in daily life context, pain diaries consider the investigation of pain fluctuation within a day and also between different days which allows to depict patient's pain course experience very precisely.

Thirdly, pain is a uniquely personal experience and therefore relies on patients' self-report of pain (Kahneman, Fredrickson, Schreiber, & Redelmeier, 1993). For this reason, pain diaries offer a patient centered approach. Results have shown that electronic pain diaries enable people to investigate other questions than questionnaire data such as pain behavior and the psychosocial determinants of pain (Peters et al., 2000). Since literature has demonstrated that the current emotional states influence the individual pain experience (Eich, Reeves, Jaeger, & Graff-Radford, 1985), pain diaries further include the assessment of emotions. Also, Turk and Melzack (2001) have emphasized that pain has an impact on all domains of the sufferer's life and therefore requires assessment beyond the pain level. Pain diaries address this lack by also including the recording of pain related thoughts, feelings, and activities (Jensen & Karoly, 2014). In effect, pain diaries are client-centered and take into

account environmental and individual features. This allows to seek variables which influence change in pain over time (Jensen & Karoly, 2014).

Taken together the use of pain diaries offers significant advances over and above the use of questionnaires and provides additional opportunities for the realization of an improved pain assessment.

1.3 Validation of Pain Diaries

However, pain diaries still lacking in reliability and validity. Content validity of pain diary items is currently understudied and remains to be tested. Indeed, it is necessary to verify if pain diary items assess what they intend to measure. The validity can be examined in two ways, following a quantitative approach and a qualitative approach.

1.3.1 Quantitative investigation of validity.

Content validity displays internal validity which is given if the item reflects the intended theoretical construct in both content and scope (Johnston et al., 2014). Further, discriminant validity is mandatory to distinguish the predictor and the outcome, otherwise it inflates the research findings (Lauwerier et al., 2015) and theory building becomes solely speculative (Goubert, Crombez, & Van Damme, 2004; Wideman, Adams, & Sullivan, 2009). Moreover, it is essential to establish the validity of an instrument to make it acceptable for future use and the practical application. (McKenzie, Wood, Kotecki, Clark, & Brey, 1999). Nevertheless, content validity has often been overlooked, whereas other forms such as construct, and criterion validity are more likely to be investigated (Haynes, Richard, & Kubany. 1995; Wiering, Boer, & Delnoij, 2017). To address this objective, the discriminant content validity method (DCV), developed by Johnston et al. (2014) is a reliable method to verify the accuracy of theory-based items. By using this method, it is tested whether each item distinctively associates to its intended theoretically construct.

1.3.2 Qualitative investigation of validity.

Pain perception differs in every individual and is controlled by a variety of variables. For this reason, the diaries particularly assess subjective perceptions and sensations. To see how well the diaries measure this subjective perception, a patient- centered approach is helpful. This patient- centered approach can be addressed via a cognitive interview. The growing use of cognitive interviews points to the importance of qualitative data for assessing and contributing to the validity and reliability in developing instruments (Knafl et al., 2007). Henceforth, cognitive interviews (CI) allow to increase the understanding of the participant's thought processing. The aim of this approach is to improve the accuracy of the items by using the patient's feedback to develop client- centered standardized measures of pain (Amtmann et al., 2017). Indeed, the analyses aim to better understand how individuals interpret and respond to pain diary items which helps to locate unclear formulations. Previous studies described the use of CI to revise items and to modify existing instruments (Dietrich & Ehrlenspiel, 2010; Karabenick et al., 2007)

1.3.2.1 Combination of qualitative and quantitative validation of pain diaries.

As a whole, we applied a combination of CI and DCV on a previously developed pain diary (further called the PainDiary) to investigate its content validity. The investigated pain diary, so called PainDiary, consists of two versions, a 25 item "ecological momentary assessment" (EMA) version and a 26 item "end of the day diary" (EDD) version. The items of both timeframes are intended for people experiencing acute pain, chronic pain and no pain. The items were assigned to twelve constructs. The defined constructs were "pain severity", "fatigue", "pain related disability", "worry about pain", "pain catastrophizing", "pain vigilance", "avoidance behavior", "activity engagement", "flow experience", "negative affect", "positive affect" and "other".

Overall, we integrated a qualitative and quantitative approach to investigate the PainDiary.

On the one hand, the quantitative approach of the DCV helps to bring data across items into a

transparent and reproducible standard metric to make it easier to identify common concerns

among items (Christodoulou, Junghaenel, DeWalt, Rothrock, & Stone, 2008). On the other

hand, the data of the CI demonstrates the results of the qualitative, client-centered

investigation, which provides a subjective perspective of the clarity of the items. This

combination helps to detect and improve possible concerns of the items used in the

PainDiary.

1.4 Hypothesis

We established two separate studies to investigate the content validity of the PainDiary

via a quantitative and qualitative method. The DCV investigation is based on a clearly defined

hypothesis, whereas the CI follows an explorative approach.

1.4.1 Study 1: Discriminant content validity.

Building upon the intention of the theory-based item construction, it was hypothesized

to identify solely pure items. In other words, each item would only reflect the intended

construct and would be significantly distinctive from the competing constructs.

1.4.2 Study 2: Cognitive interview.

The CI aims to detect weaknesses or lacks in clarity by approaching the investigation

in an explorative way.

2. Study 1

2.1 Methods

2.1.1 Participants.

The recruitment of participants was carried out via Prolific (https://www.prolific.ac/), a marketplace application to advertise the participation for online studies (Peer, Brandimarte, Samat, & Acquisti, 2017). The participants had to meet the following inclusion criteria to be eligible for this study:

(2) English as their first language

(3) Willing to provide informed consent

(4) Completion of the online assessment in line with given instructions

(5) Taking at least 20 minutes to fill out the questionnaire

2.1.2 Discriminant content validity.

The DCV is a quantitative method for assessing the content of theory-based instruments. This systematic approach reports whether the items reflect the intended construct in content and scope (Johnston et al., 2014). Below, the DCV method is described in 3 steps:

2.1.2.1 Step 1: Construction of pain diary items.

The given number of items of the pain diary are allocated in two different timeframes: the "moment right now" (EMA) and the "whole day" (EDD). However, we removed these timeframes in the DCV assessment because the content of the items remained the same and the information of interest was pointed out better without the timeframes. The items were assigned to twelve constructs. The defined constructs were "pain severity", "fatigue", "pain related disability", "worry about pain", "pain catastrophizing", "pain vigilance", "avoidance behavior", "activity engagement", "flow experience" and "other". Additionally, the two constructs "negative affect" and "positive affect" were established to examine twelve items

assessing various emotions. Find the items belonging to their theoretically intended

constructs listed below (Table 1).

Table 1

The PainDiary items aligned to their intended constructs

Construct	Item		
	EMA		**EDD**
Pain severity	1.	How much pain did you experience just before the phone went off?	1. How much pain did you experience today?
Fatigue	2.	How fatigued did you feel just before the phone went off?	2. How fatigued did you feel today?
Pain related disability	3. 4.	How much did your pain bother you just before the phone went off? How much did your pain interfere with your activities just before the phone went off?	3. How much did your pain bother you today? 4. How much did your pain interfere with your planned activities today?
Avoidance behaviour	5.		5. How much did you avoid movements of the body part of pain today?
Worry about pain	6.	How much did you worry about your pain just before the phone went off?	6. How much did you worry about your pain today?
Pain catastrophizing	7.	How afraid were you that your pain would worsen just before the phone went off?	7. How afraid were you today that your pain would worsen?
Pain vigilance	8.	How much did your pain draw your attention just before the phone went off?	8. How much did your pain draw your attention today?
Activity engagement	9.	How engaged were you in the activity you performed just before the phone went off?	9. How engaged were you in the activities you performed today?
Flow experience	10. 11. 12. 13.	I felt just the right amount of challenge in the activity I performed just before the phone went off. I felt totally absorbed in the activity I was doing just before the phone went off. My thoughts/activities ran fluidly and smoothly just before the phone went off. The right thoughts/movements occurred of their own accord just before the phone went off.	10. I felt just the right amount of challenge in the activity I performed today. 11. I felt totally absorbed in the activities I was doing today. 12. My thoughts/activities ran fluidly and smoothly today.

		13. The right thoughts/movements occurred of their own accord today.
	14. The activity I performed just before the phone went off was important.	
		14. The activities I performed today were important.
Positive affect	15. Just before the phone went off, I felt Glad?	15. Today, I felt Glad?
	16. Just before the phone went off, I felt Enthusiastic?	16. Today, I felt Enthusiastic?
	17. Just before the phone went off, I felt Happy?	17. Today, I felt Happy?
	18. Just before the phone went off, I felt Relaxed?	18. Today, I felt Relaxed?
	19. Just before the phone went off, I felt Strong?	19. Today, I felt Strong?
	20. Just before the phone went off, I felt Proud?	20. Today, I felt Proud?
Negative affect	21. Just before the phone went off, I felt Afraid?	21. Today, I felt Irritated?
	22. Just before the phone went off, I felt Irritated?	22. Today, I felt Angry?
	23. Just before the phone went off, I felt Angry?	23. Today, I felt Powerless?
	24. Just before the phone went off, I felt Powerless?	24. Today, I felt Sad?
	25. Just before the phone went off, I felt Sad?	25. Today, I felt Nervous?
	26. Just before the phone went off, I felt Nervous?	26. Today, I felt Afraid?

2.1.2.2 Step 2: Construct definitions.

Each construct was defined by using the definitions as provided in the Online Oxford Living Dictionaries for English (https://en.oxforddictionaries.com assessed on 21/2/2018). When necessary, the definitions were slightly adapted to the context of pain. No definition for "flow experience" was available in the Online Oxford Living Dictionaries for English. For that reason, we based our description on the definition by Csikszentmihalyi (1990). We chose the following definitions. All definitions are shown in Table 2.

Table 2

Construct definitions

Construct	Definition
Pain severity	The intensity or severity of pain
Fatigue	Extreme tiredness resulting from mental or physical exertion or illness
Pain related disability	Being limited in your movements, senses or activities due to pain
Worry about pain	Feel troubled or anxious about actual or potential pain or pain-related problems
Pain catastrophizing	View or present pain or pain-related problems as considerably worse than it actually is
Pain vigilance	The action or state of keeping careful watch for possible pain
Positive affect	Positive emotions
Negative affect	Negative emotions
Pain avoidance behavior	The action of preventing pain from happening
Activity engagement	The action of being engaged in an activity
Flow experience	The state in which people are so involved in an activity that nothing else seems to matter; the experience itself is so enjoyable that people will do it even at great cost, for the sheer sake of doing it.

2.1.2.3 Step 3: Rating scale of items.

In line with the practice of Johnston et al. (2014), a combined rating scale was established. Firstly, participants had to judge whether an item assesses a particular construct ("yes" = 1, or "no" = -1). Secondly, they were asked to complete a confidence rating, in which the participants evaluate to what extend they were confident in their initial rating using an 11-point scale (0 = 0 % confidence to 10 = 100 % confidence). An *outcome score* was calculated for the link between each item and each construct by multiplying the code of their answer for "yes" or "no" (1; -1) with the respective "confidence" level (0-10). This score ranges from -10 representing very certain that the item does not assess the construct opposed to +10 which reflects a very confident rating that the item measures the construct.

2.1.3 Self-report measures.

The online assessment further included three more self-reported measures: demographic variables, the chronic pain grade scale and detection of careless responding.

2.1.3.1 Demographic variables.

The demographic variables participants were asked to fill in included: age, gender, first language, country of residence, ethnicity, nationality, profession, educational background, and health status including existence of diagnosis of chronic pain.

2.1.3.2 Chronic pain grade scale (CPGS).

The CPGS (von Korff, Ormel, Keefe, & Dworkin, 1992) assesses pain and allows a comparison between pain and health. The overall dimension measures chronic pain severity, including the two subscales pain intensity and pain-related disability, scoring on a 11-point Likert Scale. The questionnaire consists of 7 items and addresses a recall period of 3-6 months. See Appendix G.

2.1.3.3 Detection of careless responding.

For the detection of careless responding, two manipulation checks were implemented (Meade & Craig, 2012). In particular, three items of the Instructional Manipulation Check were presented in between the DCV items (Oppenheimer, Meyvis, & Davidenko, 2009). Furthermore, participants' compliance and accuracy were checked by asking them how much attention they paid when responding to the DCV items and whether they estimate their data as reliable (Meade & Craig, 2012).

2.1.4 Procedure.

The official ethical guidelines of the Ethics Review Panel of the University of Luxembourg were followed, and the study was approved by the Psychology Department of the University of Luxembourg beforehand. The online survey was hosted via LimeSurvey 2.00, a link of the survey was shared via Prolific Academic. After reading the information

sheet, the consent form had to be approved by each participant before starting the

questionnaire. Following, participants received instructions of the DCV method illustrated by

two examples on how the DCV can be completed. After the instructions, participants were

provided with the item set consisting of all 26 items which were assigned in a random order.

Also, the constructs, provided above each item, were presented in a random order for each

participant. After performing the DCV questions, participants were asked to fill in

demographic information and questions to detect careless responding. As a reward for their

contribution, participants received two English pounds. The study was completed in a single

session taking on average 37.14 minutes (*SD* 14.41).

2.1.5 Statistical analyses.

All data were analyzed using the SPSS 24.0 statistical package. One-sample t-tests

allowed to investigate the relation between each item with each theoretical construct. A one-

sample t-test was conducted to determine whether the mean confidence score assigned to the

item for each construct was significantly different from 0. This was checked for each item on

each construct independently. A positive significant t-value indicated that the item measures

the construct, whereas a negative significant t-value indicated an item not measuring the

construct. Items were identified as pure ones when they measure the target construct

(significantly positive t-value) and not the competing targets (significantly negative t-value).

Mixed items indicated uncertainty or even disagreement of the judges.

2.2 Results

2.2.1 Participants.

Before data analysis, the dataset including 32 participants was checked for cases

which did not fulfill the inclusion criteria. One participant was excluded because the data

were considered unreliable (scoring on one item the same value for each construct); 6

participants completed the questionnaire in less than 20 minutes; 2 participants indicated at the end of the questionnaire that the data should not be used, and 2 participants failed in the manipulation checks of careless responding and were also deleted from the dataset. In total, 21 cases remained for the data analysis (mean age of 30 years, 11 female, 9 male, 1 other). The majority of the participants reported to be Caucasian ($N = 19$) while two participants indicated other ethnicities (Latino and Biracial). The marital status was fairly distributed single ($N = 7$), in a relationship ($N = 5$) and married ($N = 9$). All of them indicated English as their first language, aligned to the following nationalities: United Kingdom ($N = 15$), United States ($N = 5$) and Australia ($N = 1$). More than the half of the participants followed a university program ($N = 17$). The health status was distributed fairly scoring on all levels (Excellent health: $N = 3$; very good health: $N = 7$; good health: $N = 2$; fair health: $N = 6$; poor health: $N = 3$)

2.2.2 Chronic pain grade scale (GPGS).

On the GCPS, participants rated their current pain as 2.39 ($SD = 2.44$). Participants scored their worst pain during the past six months as 5.48 ($SD = 2.44$) and their average pain as 3.33 ($SD = 2.39$). Furthermore, participants reported that pain interfered on average 3.86 (SD = 3.25) with daily activities, changed their ability to take part in recreational, social and family activities on average 3.48 ($SD = 3.49$) and changed their ability to work on average 3.48 ($SD = 3.30$). Finally, participants reported to be on average 26 days (SD = 53) days off normal task. Calculation of the pain grade showed that the participants were classified in grade 0 ($N = 8$), grade 1 ($N = 7$), grade 2 ($N = 2$), grade 3 ($N = 1$), grade 4 ($N = 3$).

2.2.3 Content validity of each item.

The content validity yielded the below indicated means of the confidence rating for each item on each construct (Table 3). The polarity shows whether the item loaded on the construct

(positive value = yes; negative value = no) and the level of significance shows if its

significantly different from zero.

Table 3

Mean of confidence rating for each item to each construct

	Pain severity	Worry about pain	Fatigue	Pain catastro-phizing	Pain-related disability	Flow	Neg. affects	Pos. affects	Pain avoi-dance behave.	Pain vigilance	Activity engagem.	Other
Item 1 - Pain severity	8,76***	-0,38	-4,62**	1,67	1,43	-5,76***	4,19**	-6,29***	-2,48	0,19	-4,67**	-6,62***
Item 2 - Fatigue	-4,24**	-5,29***	9,29***	-4,67**	-2,86	-4,62**	2,48	-4,76**	-4,14**	-3,67*	-3,29	-2,90
Item 3 - Pain-related disab.	7,62***	7,19***	-5,33***	3,24*	3,48*	-4,71***	5,19**	-3,57*	1,52	3,81*	-1,71	-4,86**
Item 4 - Pain-related disab.	6***	3,33*	-1,29	0,29	7,14***	-1,10	5,52***	-3,43*	4,10**	3,76*	4,14*	-4,05**
Item 5 - Avoidance behav.	1,38	3,57*	1,29	0,57	6,86***	-4,48**	1,67	-6,24***	7,10***	5,05***	1,34	-6,14***
Item 6 - Worry about pain	-1,24	8,57***	-6,19***	3,57*	-1,33	-3,67*	2,95	-3,71*	2,14	4,05**	-2,24	-6,52***
Item 7 – Catastro-phizing	2,81	8,62***	-5,05**	3,71*	0,1	-4,29**	5,67***	-4,33**	1	3,43*	-1,05	-5,67***
Item 8 - Pain vigilance	7,38***	6,67***	-3,33*	1,90	3,24*	-1,86	5,52***	-3,81**	1,81	4,95**	-0,48	-3,62*
Item 9 - Activity engagem.	-5,52***	-1,95	-2,14	-5,19***	-4,52**	4,10*	-3,29	-2,24	-3,52*	-3,67*	8,19***	-4,10**
Item 10 - Flow experience	-3,29*	-4,57**	-3,48*	-5**	-3,71*	2,00	-4**	4,76**	-4,52**	-2,90	6,19***	-3,52*
Item 11 - Flow experience	-4,09**	-2,48	-4,52**	-6,10***	-6,86***	7***	-3,43*	3,90*	-4,10*	-3,38*	6,43***	-3,00
Item 12 - Flow experience	-4,76**	-1,48	-1,90	-4,81***	-3,38*	3,57*	-2,38	3,76*	-3,76**	-4*	4,95**	-3,38*
Item 13 - Flow experience	-4,86**	-3,71*	-5,76***	-4,05*	-5,52***	4,14*	-3,24	2,71	-3,86**	-4,62**	2,62	-3,14*
Item 14 - Flow experience	-7,05***	-7***	-6,33***	-6,90***	-7***	1,43	-5,62***	2,38	-6,29***	-5,29**	4,76**	-5,76***
Item 15 - Positive affect	-5,57***	-2,43	-5,91***	-5,38***	-6,24***	-1,57	-5,67***	6,76***	-6,10***	-6,29***	-1,76	-3,10
Item 16 - Positive affect	-6,14***	-3,43*	-4,29**	-6,29***	-6,33***	-0,29	-4,71**	7,76***	-4,71**	-5,90***	-0,19	-4,86**
Item 17 - Positive affect	-4,48**	-3,43*	-4,48**	-5,29***	-6,05***	-1,24	-3,95*	9,05***	-5,24**	-4,67**	-3,43	-2,76
Item 18 - Positive affect	-3,57*	-0,14	-1,24	-3,48*	-4,38**	-1,05	-4,71**	8,24***	-3,95**	-2,19	-2,19	-2,24
Item 19 - Positive affect	-2,24	-2,33	0,95	-3,48*	-4,90**	-3,19*	-6,19***	6,05***	-4,57**	-3,71*	-3,14	-1,43
Item 20 - Positive affect	-7,38***	-6,48***	-7,24***	-7***	-7,29***	-1,52	-5,71***	6,71***	-6,90***	-7,10***	-2,43	-2,86
Item 21 - Negative affect	-4,38**	2,33	-6,81***	1,76	-4,14**	-3,33	7,05***	-4,67**	-3,14	-1,86	-2,81	-4,14**

Item 22 - Negative affect	-4,10**	-3,48*	-2,43	-3,67*	-3,33*	-1,81	7,29***	-5,90***	-3,24*	-2,95	-0,67	-2,90
Item 23 - Negative affect	-4,38**	-4,14**	-5,90***	-2,19	-4,33**	-4,33**	7,71***	-5**	-5**	-3,86*	-2,86	-3,38*
Item 24 - Negative affect	-3,48*	-1,38	-2,86	-1,95	-3,10*	-3,52*	7,19***	-5**	-3,33*	-3,48*	-1,33	-2,81
Item 25 - Negative affect	-3,95*	-2,05	-3,67*	-2,67	-3,90*	-2,62	6,57***	-2,57	-5,05**	-3,38	-1,38	-2,43
Item 26 - Negative affect	-6,62***	3,33	-4,90**	-3,14*	-5,67***	-1,38	5,81**	-5,57**	-3,43	-3,00	-0,29	-3,76*

Note. *p<.05 **p<.01 ***p<.001

Pain severity.

1. *How much pain did you experience just before the phone went off/ today?*

The item showed a positive mean for the target construct "pain severity" ($M = [8,76]$) which statistically significantly differed from zero, $t(20) = [18.35]$, p = [.000]. Further, it was significantly different from zero for the construct "negative affect" ($M = [4.19]$), t(20) = [2.95], $p = [.008]$.

Fatigue.

2. *How fatigued did you feel just before the phone went off/ today?*

The item scored clearly on the intended construct "fatigue" ($M = [9.29]$) which statistically significantly differed from zero, $t(20) = [21.51]$, $p = [.000]$.

Pain related disability.

3. *How much did your pain bother you just before the phone went off/ today?*

The item showed a positive mean for the target construct "pain- related disability" ($M = [3.48]$) which statistically significantly differed from zero, $t(20) = [2.433]$, $p = [.024]$. Nevertheless, it also scored significantly on the constructs "pain severity" ($M = [7.62]$), $p = [.000]$, "worry about pain" ($M = [7.19]$), $p = [.000]$, "pain catastrophizing" ($M = [3.24]$), $p =$

[.039], "negative affect" (M = [5.19]), p = [.002], and "pain vigilance" (M = [3.81]), p = [.019].

4. *How much did your pain interfere with your activities just before the phone went off/ today?*

The item showed a positive mean for the target construct "pain-related disability" (M = [7.14]) which statistically significantly differed from zero, $t(20)$ = [8.53], p = [.000]. Further, it also scored significantly on the constructs "pain severity" (M = [6]), p = [.000], "worry about pain" (M = [3.33]), p = [.042], "negative affect" (M = [5.52]), p = [.000], "pain avoidance" (M = [4.10]), p = [.007], "activity engagement" (M = [4.14]), p = [.015], and "pain vigilance" (M = [3.76]), p = [.018].

Avoidance behavior.

5. *How much did you avoid movements that cause pain today?*

The item showed a positive mean for the target construct "avoidance behavior" (M = [7.10]) which statistically significantly differed from zero, $t(20)$ = [6.86], p = [.000]. Further, it also scored significantly on the constructs "pain-related disability" (M = [6.86.]), p = [.000], "pain vigilance" (M = [5.05]), p = [.000], and "worry about pain" (M = [3.57]), p = [.022].

Worry about pain.

6. *How much did you worry about your pain just before the phone went off/ today?*

The item showed a positive mean for the target construct "worry about pain" (M = [8.57]) which statistically significantly differed from zero, $t(20)$ = [14.28], p = [.000]. Further, it also scored significantly on the constructs "pain catastrophizing" (M = [3.57]), p = [.023], and "pain vigilance" (M = [4.05]), p = [.007].

Pain catastrophizing.

7. *How afraid were you that your pain would worsen just before the phone went off/*

    today?

The item showed a positive mean for the target construct "catastrophizing" ($M =$ [3.71]) which statistically significantly differed from zero, $t(20) =$ [2.59], $p =$ [.018]. Further, it also scored significantly on the constructs "worry about pain" ($M =$ [8.62]), $p =$ [.000], "negative affect" ($M =$ [5.67]), $p =$ [.000], and "pain vigilance" ($M =$ [3.43]), $p =$ [.029].

Pain vigilance.

8. *How much did your pain draw your attention just before the phone went off/*

    today?

The item showed a positive mean for the target construct "pain vigilance" ($M =$ [4.95]) which statistically significantly differed from zero, $t(20) =$ [3.90], $p =$ [.001]. Further, it also scored significantly on the constructs "pain severity" ($M =$ [7.38]), $p =$ [.000], "worry about pain" ($M =$ [6.67]), $p =$ [.000], "negative affect" ($M =$ [5.52]), $p =$ [.000], "pain-related disability" ($M =$ [3.24]), $p =$ [.036].

Activity engagement.

9. *How engaged were you in the activity you performed just before the phone went*

    off/ today?

The item showed a positive mean for the target construct "activity engagement" ($M =$ [8.19]) which statistically significantly differed from zero, $t(20) =$ [8.62], $p =$ [.000]. Further, it also scored significantly on the construct "flow" ($M =$ [4.10]), $p =$ [.015].

Flow experience.

10. I felt just the right amount of challenge in the activity I performed just before the

phone went off/ today.

The item did not showed a positive mean for the target construct "flow" (M = [2.00])

which statistically significantly differed from zero, $t(20)$ = [1.27], p = [.217], but instead it

showed significance for the construct "activity engagement" (M = [6.19]), p = [.00], and

"positive affect" (M = [4.76]), p = [.002].

11. I felt totally absorbed in the activity I was doing just before the phone went off/

today.

The item showed a positive mean for the target construct "flow" (M = [7]) which

statistically significantly differed from zero, $t(20)$ = [6.29], p = [.000], but also for the

construct "activity engagement" (M = [6.43]), p = [.000], and "positive affect" (M = [3.90]),

p = [.02].

12. My thoughts/activities ran fluidly and smoothly just before the phone went off/

today.

The item showed a positive mean for the target construct "flow" (M = [3.57]) which

statistically significantly differed from zero, $t(20)$ = [2.53], p = [.02], but also for the

construct "activity engagement" (M = [4.95]), p = [.002], and "positive affect" (M = [3.76]),

p = [.02].

13. The right thoughts/movements occurred of their own accord just before the phone

went off/ today.

The item showed a positive mean for the target construct "flow" (M = [4.14]) which

statistically significantly differed from zero, $t(20)$ = [2.811], p = [.011].

14. *The activity/ies I performed just before the phone went off/ today was/were*

   important.

The item showed a positive mean only for the construct "activity engagement" ($M =$ [4.76]) which statistically significantly differed from zero, $t(20) =$ [3.04], $p =$ [.007] and did not score on the target construct "flow".

Positive affect.

15. *Just before the phone went off/ Today, I felt Glad?*

The item showed a positive mean for the intended construct "positive affect" ($M =$ [6.76]) which statistically significantly differed from zero, $t(20) =$ [5.99], $p =$ [.000].

16. *Just before the phone went off/ Today, I felt Enthusiastic?*

The item showed a positive mean for the intended construct "positive affect" ($M =$ [7.76]) which statistically significantly differed from zero, $t(20) =$ [9.76], $p =$ [.000].

17. *Just before the phone went off/ Today, I felt Happy?*

The item showed a positive mean for the intended construct "positive affect" ($M =$ [9.05]) which statistically significantly differed from zero, $t(20) =$ [19.66], $p =$ [.000].

18. *Just before the phone went off/ Today, I felt Relaxed?*

The item showed a positive mean for the intended construct "positive affect" ($M =$ [8.24]) which statistically significantly differed from zero, $t(20) =$ [13.44], $p =$ [.000].

19. *Just before the phone went off/ Today, I felt Strong?*

The item showed a positive mean for the intended construct "positive affect" ($M =$ [6.05]) which statistically significantly differed from zero, $t(20) =$ [5.06], $p =$ [.000].

20. *Just before the phone went off/ Today, I felt Proud?*

The item showed a positive mean for the intended construct "positive affect" ($M =$ [6.71]) which statistically significantly differed from zero, $t(20) =$ [5.74], $p =$ [.000].

Negative affect.

21. Just before the phone went off/ Today, I felt Afraid?

The item showed a positive mean for the construct "negative affect" (M = [7.05]) which statistically significantly differed from zero, $t(20)$ = [5.82], p = [.000].

22. Just before the phone went off/ Today, I felt Irritated?

The item showed a positive mean for the construct "negative affect" (M = [7.29]) which statistically significantly differed from zero, $t(20)$ = [6.92], p = [.000].

23. Just before the phone went off/ Today, I felt Angry?

The item showed a positive mean for the construct "negative affect" (M = [7.71]) which statistically significantly differed from zero, $t(20)$ = [8.73], p = [.000].

24. Just before the phone went off/ Today, I felt Powerless?

The item showed a positive mean for the construct "negative affect" (M = [7.19]) which statistically significantly differed from zero, $t(20)$ = [7.41], p = [.000].

25. Just before the phone went off/ Today, I felt Sad?

The item showed a positive mean for the construct "negative affect" (M = [6.57]) which statistically significantly differed from zero, $t(20)$ = [5.31], p = [.000].

26. Just before the phone went off/ Today, I felt Nervous?

The item showed a positive mean for the construct "negative affect" (M = [5.81]) which statistically significantly differed from zero, $t(20)$ = [4.11], p = [.000].

Find all data for the one sample t-tests in Appendix A.

2.3 Discussion

The study investigated the content of items from the PainDiary using the DCV method (Dixon et al., 2007; Johnston et al., 2014). The results showed that 14 items distinctively measured the intended construct. Nevertheless, 11 items (Item 1, 3, 4, 5, 6, 7, 8,

9, 10, 11, 12) loaded not only on their intended construct, but also on competing constructs. One "flow" item *"The activity/ies I performed was/were important."* reflected another construct than intended. It loaded significantly on the construct "activity engagement" which is very closely related to "flow experience". For that reason, we would not judge this identification as problematic. We found that all emotion items were correctly identified, such as the items for the construct "fatigue" and one "flow" item. Interestingly, it was found a big overlap for all "flow" and "activity engagement" items on the constructs "flow", "activity engagement" and "positive affect". Certainly, these constructs are really strongly related and intertwined which makes the overlap highly comprehensible (why they show this overlapping). These findings are helpful for the interpretation process and have to be taken into consideration to draw further conclusions. The 8 mixed items shall be discussed separately in the following paragraph.

The items loading on more than the intended construct were the ones for "pain-related disability" item 4 loaded on seven constructs and item 3 on six constructs. Further, five constructs were identified for the item of "pain vigilance". The items for "avoidance behavior" and "catastrophizing" have been loaded on four constructs. The item for the construct "worry about pain" also scored on the constructs "pain vigilance" and "catastrophizing". Last, the item for "pain severity" and "worry" loaded not only on their target construct, but also on the construct "negative affect". However, almost all of them loaded the highest on their target construct. If we would set the threshold of the level of significance at .001 we would find that most of the items are tightly associated with their target construct only. Hence, three of the items (Item 1, Item 6, Item 9) would solely score on their target construct.

However, the overlap of certain item is not very surprising. Taking a closer look at the data, it shows that the main outcome measure "pain severity" is solely overlapping with

negative affect. Obviously, these two constructs are very suitable for the item and does not mean that it has to be mutually exclusive. More important is the fact that item1 ("pain severity") does not load on any other construct which might be used as predictor like for example "pain catastrophizing" etc. The fact, that the other possible predictors show certain overlaps is not so unexpected either because they show a certain association which has to be considered and researchers should be aware of.

The conclusions are based on the statistically significant positive t-value. However, to be certain that the item does not load on another construct, all negative t-values need to be significant as well. This was not consistently given. On the one hand, this can be due to the small sample size, on the other hand, it leaves some room for uncertainties about the "pureness" of the items which has to be taken into account.

Looking at the limitations of the study, mainly the relatively small sample size ($N = 21$) should be considered, although similar sample sizes ranging between $N = 17 - 38$ can be found in comparable studies (but see Johnston et al. (2014), with similar sample sizes ranging between $N = 17 - 38$). Further, the sample consisted of a very narrow type of people (Caucasians with internet access) which were voluntary taking part in the online survey, nevertheless it also included some chronic pain patients which are considered as the target group for the future use of the items. However, it did not include experts or a wider range of nationalities which does not necessarily reflects a limited representation of the population.

Next, the design of the online survey was quite complex, and some participants indicated in the remarks that they were struggling to comprehend what was asked for. That could have triggered some demand characteristics which might have led some participants to indicate as many constructs as possible when imagining a possible link. Consequently, this this might explain the overlaps. However, the design was already used in previous studies and proved its usability (Johnston et al., 2014).

To conclude, the results revealed 14 pure items and 12 items which should be redefined or at least considered since they measure more than one construct. However, these psychometric findings should be complemented by a qualitative assessment to get a different insight in the cognitive process of the respondents and to assess the clarity of the items.

3. Study 2

3.1 Methods

3.1.1 Participants.

Participants were recruited from two sources: flyer distribution (see Appendix B) on Campus Belval at the University of Luxembourg to address healthy University students and an internet posting on the website science.lu (http://science.lu/) (see Appendix C) to reach chronic pain patients. Interested candidates were provided with a screening form (see Appendix F) to indicate more information, depending on their characteristics to see whether they fulfilled the inclusion criteria. The aim was to reflect a wide range of varieties with respect to sociodemographic and diagnosis. Accordingly, we included both the participants of general population, that was suffering from acute pain (delayed onset muscle soreness (DOMS)) after induction and chronic pain patients. The inclusion criteria were the following:

Category 1: General population: University students

(1) Being at least 18 years of age

(2) English being first language or at least C1 level

(3) Willing to provide signed informed

(4) Allowing the interview to be audio-recorded

Category 2: Target group: chronic pain patients

Inclusion criteria 1-4 and additionally

(5) Suffering from chronic pain for over 6 months

3.1.2 Cognitive interview.

The cognitive interview protocol pursues a standardized methodology, which was applied across all participants (Appendix I). The cognitive interview consisted of all 26 items and additionally, the two instructions (of EMA and EDD) which aim to introduce the user to the pain diary. The interviewer asked for specific information using cognitive probes

provided by Willis (2004). The selected probes were comprehension probes, paraphrasing, confidence judgement, recall probes, specific probes and general probes.

The CI protocol had the following structure consisting of 7 steps:

3.1.2.1 Step 1: Introduction.

In step 1, the method was introduced. The introduction outlined the importance that this interview was not about collecting information about the participant itself. Rather, the participant was asked to help to detect lacks in clarity.

3.1.2.2 Step 2: Instructions.

To test the clarity of the instructions (EMA and EDD) two different kind of probes were presented: (1) Paraphrasing: *What is the instruction telling you?* (2) Specific Probe: *Do you think the instructions are clear to most people? What would make the instruction easier to understand?*

3.1.2.3 Step 3: Twelve items assessing theory-based constructs.

The following twelve items which are based on theory-based constructs, were all investigated in the same manner. We were aware that this results in being a rather repetitive procedure which can risk a replicating responding behavior. In order to avoid triggering these repetitive response patterns, the probes were designed in a varied manner by combining closed questions, confidence judgement, recall probes, sentence completion tasks and specific probes. (1) Completion task: *What period did you take into account to answer the question?* (2) Confidence judgement: *How sure are you of your answer?* (3) Recall probe: *Did you think about specific moments? Which ones?* (4) Closed questions: *Did the question apply to you? Did you feel uncomfortable to talk about it? Do you see any other problem that you want to mention?* (5) Specific probe: *In general, what difficulties could occur with understanding this item? Can you think of an easier way to word the question?*

3.1.2.4 Step 4: Emotions.

The items assessing emotions were analyzed for clarity, assumption, sensitivity and other problems. We chose a quantitative coding scheme including closed questions. The following probes were used. (1) Closed questions: *Do you think this emotion is clear to most people? Did the question apply to you? Did you feel uncomfortable to talk about it? Do you see any other problem that you want to mention?*

3.1.2.5 Step 5: Comparison of response format.

A major interest was the comparison of two different response formats: numerical scale (NS) versus visual analogue scale (VAS). After assessing three specific probes for each scale, a comparison between the scales followed. (1) Specific probes: *How easy or difficult was it to choose an answer? What do the numbers on the scale mean to you? Are there any confusing things on the pain scale?* (2) Specific probe/ Comparison: *Which pain scale do you prefer? Why?*

3.1.2.6 Step 6: Additional questions or concerns.

In the end, a general probe was introduced to allow further remarks or suggestions. (1) General probe: *Is there anything else that you would like to suggest that would help us to improve these items for future use?*

3.1.2.7 Step 7: Short debrief.

The short debriefing announced that the interview had ended, provided the opportunity to share some feedback and included a thank-you note.

3.1.3 Self-report measures.

Participants responded to a short questionnaire including demographic variables and the chronic pain grade scale.

3.1.3.1 Participant characteristics.

The following demographic variables were assessed: age, gender, first language, proficiency of English language, country of residence, ethnicity, nationality, profession, educational background, health status including existence of diagnosis of chronic pain, duration of chronic pain, symptom severity, location, comorbidity, medication.

3.1.3.2 Chronic pain grade scale (CPGS).

The CPGS (von Korff, Ormel, Keefe, & Dworkin, 1992) assesses pain to allow a comparison between pain and health. The overall dimension measures chronic pain severity, including the two subscales pain intensity and pain-related disability, scoring on a 11-point Likert Scale. The questionnaire consists of 7 items and addresses a recall period of 3-6 months. See Appendix G.

3.1.4 Procedure.

The study was preliminarily approved by the Psychology Department of the University of Luxembourg beforehand.

3.1.4.1 Invitation of participants.

After being contacted by interested candidates, we provided possible participants with a standardized screening form to collect more information. If fulfilling the above-mentioned criteria, participants were invited to test the PainDiary for two days in daily life context outside of the lab on a smart phone. The aim was to allow a realistic field testing phase before conducting the interviews.

3.1.4.2 DOMS training for healthy participants.

Before the field testing phase, healthy participants were further invited to participate in a DOMS training. This training session aimed to induce muscle soreness on a randomized side of the shoulders. This training followed a standardized training protocol. The participants had to repeat a slow shoulder movement five times for each set on a Technogym

Delts machine. Starting from zero kilograms, the weight was increased in steps of five kilograms until the participant reached the point of volitional fatigue or completed 11 sets. During the exercises, verbal encouragements were given by the test leader. In effect, this resulted in muscle soreness to make it more appropriated to fill in the pain diary. Thus, heathy students could also reflect on the pain items (see Appendix G for the DOMS training protocol). Since the chronic pain patients suffered already from pain, the DOMS training did not apply for this group.

3.1.4.3 Testing phase of PainDiary.

During the testing phase, the participants had to complete 8 EMAs per day and each day one EDD in the end of the day. We were particularly interested in the comparison of two different kinds of response formats, such as the numerical scale (NRS) versus the visual analogue scale (VSA). Therefore, we randomly assigned those two scales during the two days, so that after the two days, all participants received 8 times the EMA with NRS and 8 times with VAS, the EDD was completed one evening with the NRS and the other evening with the VAS. Overall, the participants tested all items of both scales at the same amount of times.

3.1.4.4 Cognitive interview.

After the testing phase, the face-to-face cognitive interviews took place on Campus Belval at the University of Luxembourg and lasted approximately 60 minutes. All 26 items were tested by each participant. After participants gave their informed consent, they filled in a questionnaire including some sociodemographic information and the chronic pain grade scale. To begin, the interviewer read a short introduction paragraph providing all explanations. Afterwards, the interviewer followed the CI protocol. All interviews were audio-recorded, and notes were taken.

3.1.4.5 Interview round.

The interview round consisted of six participants: three university students and three chronic pain patients. Participants were rewarded with a 20 € voucher for their contribution (see Appendix J: Receipt for gift voucher). Participants' feedback was used to modify, delete or add items.

3.1.5 Analyses.

Descriptive statistics were used to characterize the demographics of the participants. The analysis of the content validity was based on the notes and recording of the interview. The responses of the CI were aligned to categories to assure consistency of coding, and category integrity. The items were examined for the following seven categories after Willis (2004): (1) Instructions: Look for problems with any introductions, instructions, or explanation from the respondent's point of view. (2) Clarity: Identify problems related to communicating the intent or meaning of the question to the respondent. (3) Assumptions: Determine if there are problems with assumptions made or the underlying logic. (4) Knowledge/ Memory: Check whether respondents are likely to not know or have trouble remembering information. (5) Sensitivity: Assess questions for sensitive nature. (6) Response category: Assess the adequacy of the range of responses to be recorded. (7) Other problems: Other problems not identified in 1-6. The gathered information was used to decide upon acceptation, modification or deletion of each item.

3.2 Results

3.2.1 Participant descriptive.

The demographic data shows a great range of variety. Find all the demographic characteristics listed in the table below (Table 4).

Table 4

Demographic characteristics of study 2

Nº	1	2	3	4	5	6
Category	General population	General population	General population	Chronic pain patient	Chronic pain patient	Chronic pain patient
Sex	m	f	m	m	f	m
Years of Age	30	19	19	29	39	27
Nationality	Brazil	German	Luxembourg	American	Hungarian	Luxembourg
Ethnicity	Latino, Mixed	Asian	Black	Caucasian	Caucasian	Asian
Years of education	24	13	12	19	18	21
Profession/ Study Program	M.A. Communication	B. Sc. Psychology	B. Law	M.Sc. Philosophy	Translator	Teacher
Relationship Status	Single	Single	Single	Single	Married	Single
Diagnosis	none	none	none	yes	yes	Yes
Location	-	-	-	ankle	back	back
Duration	-	-	-	2 years	3 years	2 years
Severity	-	-	-	mild	mild-severe	moderate
Comorbidity	-	-	-	Anxiety, Depression	Arthrosis, Scoliosi Scheuermann, osteophytosis	None
Medication	-	-	-	No	No	Yes

3.2.2 Chronic pain grade scale (CPGS).

The CPGS grades range from Grade 0 to Grade 5. The results revealed the following outcomes for the participants (Table 5). The findings show slightly increased grades for the chronic pain patient, whereas all healthy volunteers scored on Grade 0.

Table 5

Results: Chronic Pain Grade Scale

Nº	Category	Days of Pain	Pain Intensity Score	Disability Score	Disability Points	Classification
1	General population	1	13.33	23.33	0	Grade 0

2	General population	6	50	10	0	Grade 0
3	General population	0	13.33	0	0	Grade 0
4	Chronic pain patient	90	36.66	13.33	0	Grade I
5	Chronic pain patient	80	56.66	40.00	1	Grade II
6	Chronic pain patient	80	76.66	60	2	Grade II

3.2.3 Cognitive interview results.

3.2.3.1 Instructions.

The instructions were clear, and participants did not show any problems in understanding them. Therefore, they could clearly comprehend and express the meaning and intention of the instructions. To illustrate, participants paraphrased them correctly and were able to implement what they were supposed to do. For example (EMA): *"To pay attention to how I am feeling at the moment, to be mindful and present, to evaluate my emotions and my well-being"*. For instance (EDD): *"I have to click start to start the questionnaire, it's about summarizing the whole day such as my emotions and feelings"*.

Conclusion

The instructions were very clear. Nevertheless, all items raised huge fluctuations for the time span of the EMA. Due to big differences of interpreting "just before the phone went off", participants' answers referred to a period ranging between just a few seconds and a couple of hours, the intended time span should be specified already in the instructions:

→ Please fill out the questionnaire now! Answer the questions about how you felt and what you thought just before the phone went off (taking into account the last 5 min) as honest and accurate as possible. Click "Start" to fill out the questions.

3.2.3.2 Clarity, assumption, knowledge/memory and sensitivity.

1. Pain severity

Item 1: How much pain did you experience just before the phone went off/ today?

Clarity: This item was very clear. Except for one chronic pain patient, all participants understood the item without any uncertainties. Nevertheless, one chronic pain patient stressed that the word pain should be replaced by "discomfort" which describes his regular chronic feeling better. In his opinion, asking for pain would mean that he would be reinjured or would affect another pain source. Certainty: The certainty was rated by all participants between 70-90% for the EMA and 75-95% for the EDD. Time span: Further, the considered time span included 2-5 min for the EMA and the whole day for the EDD. Four out of six participants calculated an average to indicate their answers in the EDD. Assumption: The item applied for all participants.

Conclusion: No revision.

2. Fatigue

Item 2: How fatigued did you feel just before the phone went off/ today?

Clarity: The item was not very clear. More than the half of the participants showed uncertainties about the intended meaning of "fatigue". It was not clear whether physical, mental or an overall fatigue was asked for. Therefore, the given responses were inconsistent, and people replied in consideration of what kind of fatigue applied to them at that moment. This makes the responses very inconsistent and should be reframed. One participant suggested to make two questions out of it, one for physical fatigue and one for mental fatigue. Certainty: Next, the certainty was rated by the participants between 50-100% for the EMA and 30-100% for the EDD which was due to the lack of clarity of the definition of "fatigue". Time span: the considered time span included 1-10 min for the EMA and for the EDD it differed between the whole day and the last hours of the day. In other words, some participants made an average of the day while others rather considered the end of the days (last hours). Assumption: The item applied for EMA and EDD.

Conclusion: Revision may be needed. Suggestions:

→ How mentally fatigued did you feel just before the phone went off/ today?

3. Pain-related Disability

Item 3: How much did your pain bother you just before the phone went off/ today?

Clarity: This item was very clear. Certainty: The certainty was rated by the participants between 70-100% for the EMA and 70-100%. Time span: The considered time span included 1min to 20min for the EMA and the whole day for the EDD. Most participants again averaged on the base of specific moments while one chronic pain patient rather considered the end of the day. Assumption: The item applied for EMA and EDD. Conclusion: No revision.

Item 4: How much did your pain interfere with your activities just before the phone went off/ today?

Clarity: This item was very clear. No ambiguity has been shown. Certainty: The certainty was rated by the participants between 50-100% for the EMA and 50-100%. Time span: the considered time span included 1min to 1 hour for the EMA and the whole day for the EDD. Most participants again averaged the interference with their activity for the striking moments of the day. Assumption: The item applied for EMA and EDD. Conclusion: No revision.

5. Avoidance behavior

Item 5: How much did you avoid movements that cause pain today?

Clarity: This item was very clear. Certainty: No participant indicated any issue, same for the certainty which was rated by the participants between 90-100% for the EDD. Time span: The considered time span included the whole day for the EDD. To answer the item, people thought about different situations during the day. Assumption: The item applied for all

participants apart from one chronic pain patient who stated: *"I never avoid movements, that's no solution"*.

Conclusion: No revision.

6. Worry about pain

Item 6: How much did you worry about your pain just before the phone went off/ today?

Clarity: This item showed ambiguity. Especially the term "worry" was not clear. One participant was not sure what was meant exactly: *"to worry about the future or in general"*. Another participant showed trouble with indicating the extent of worrying. For that reason, he suggested to transform this item in a binary yes/no type question. Certainty: the certainty was rated by the participants between 80-100% for the EMA and 70-100% for the EDD. Time span: The considered time span lasted 5min to 2 hours for the EMA and the whole day for the EDD. Assumption: The item applied for all except for two chronic pain patient which outlined that they would not worry about it because they just had to accept it.

Conclusion: No revision.

7. Pain catastrophizing

Item 7: How afraid were you that your pain would worsen just before the phone went off/ today?

Clarity: This item was very clear. Certainty: The certainty was rated by the participants between 80-100% for the EMA and 90-100% for the EDD. Time span: The considered time span included less than a minute to 1hour for the EMA and the whole day for the EDD. Assumption: The item applied for all participants apart for one chronic pain patient.

Conclusion: No revision.

8. Pain vigilance

Item 8: How much did your pain draw your attention just before the phone went off/ today?

Clarity: This item was very clear, but one participant remarked that the question is quite similar to the one before and it would be helpful to transform it into a yes/no type question. To realize this remark, it could be assessed whether the pain draws attention and add as a complementary question, to which extent it interfered with the activity. Certainty: the certainty was rated by the participants between 80-90% for the EMA and 80-90% for the EDD. Time span: the considered time span included 5 min to 1 hour for the EMA and for the EDD the whole day. Again, most participants considered specific moments during the day remembered better and calculated the average for the answers on the EDD scale. Assumption: The item applied for EMA and EDD.

Conclusion: No revision.

9. Activity engagement

Item 9: How much were you engaged in the activity you performed just before the phone went off/today?

Clarity: This item was very clear. Only one participant reported difficulties to respond on the scale from 0-10. She suggested to modify the question into a binary yes/no question. Another participant noted that it was a confusing to reply on it for simple tasks. Certainty: The certainty was rated by the participants between 80-100% for the EMA and 80-100% for the EDD. Time span: The considered time span ranged from the moment itself (less than a minute) to 1 hour for the EMA and for the EDD it differed between the whole day and the last five hours of the day. Assumption: The item applied for EMA and EDD.

Conclusion: No revision.

10. Flow experience

Item 10: I felt just the right amount of challenge in the activity I performed just before the phone went off/today.

Clarity: This item was not clear. Particularly, the term "right amount" raised confusion. Each participant had at least one remark on this item. Almost all participants struggled to define the "right amount" and whether it would be possible to fulfill this criterion. Especially, the application of this item for activities in which no challenge was experienced was confusing for some participants. A participant suggested to make the item easier to understand and to avoid the term "right amount". For example: "How much concentration was necessary to perform the activity?" Certainty: The certainty was rated by all participants between 20-90% for the EMA and 20-90% for the EDD. This big fluctuation can be explained by the lack of clarity. Time span: The considered time span included 2 min to 1 hour for the EMA and the whole day for the EDD. Four out of six participants built an average to indicate the EDD. Assumption: The item applied for EMA and EDD. Conclusion: Revision may be needed. Suggestions:

→ How much concentration was necessary to perform the activity just before the phone went off/today?

→ How challenging were the activity I performed just before the phone went off/ today?

Item 11: I felt totally absorbed in the activity I was doing just before the phone went off/ today.

Clarity: A lack in clarity could be observed for this item. The term "absorbed" was understood as being extremely "*… focused and concentrated on the activity"* However, the participants noted difficulties in defining an amount of being absorbed. Another student remarked that the item would be really similar to the item "How engaged were you in the activity?" Certainty: The certainty was rated by the participants between 50-100% for the EMA and 50-100% for the EDD. Time span: The considered time span included less than a minute to 10 minutes for the EMA and the whole day for the EDD except for one student who considered only the last hours of the day. The item applied for EMA and EDD.

Conclusion: Revision may be needed. Suggestion:

→ I felt completely absorbed (=fully concentrated/focused) in the activity I was doing just before the phone went off/ today.

Item 12. My thoughts/activities ran fluidly and smoothly just before the phone went off/ today.

Clarity: This item was not clear. The term "fluidly and smoothly" was quite difficult to understand and did not show a common understanding. Some people understood it as "to be thinking without interruptions" whereas others interpreted the meaning as "to be concentrated", "to have the mind occupied", and "if obstacles occur they sort of block the fluid". Finally, one participant suggested to replace "fluidly and smoothly" by "normally". Moreover, it was confusing to name thoughts and activities together "thoughts/activities" People were struggling if it meant the thoughts about the activities or whether it meant one of both. Therefore, a participant said that it would be better to make two separate questions: one for thoughts and one for activities.

Certainty: The certainty was rated by the healthy participants between 70-100% for the EMA and 70-100% for the EDD. Whereas the chronic pain patients rated the certainty between 30-70% for EMA an EDD. Time span: the considered time span included less than a minute to 1 hour for the EMA and the whole day for the EDD except for one student who considered only the last four hours of the day. Assumption: The item applied for EMA and EDD for the healthy participants. Two chronic pain patients indicated that it would not apply to them. Conclusion: Revision may be needed. Suggestions:

→ My thoughts ran fluidly and smoothly (= normally) without being blocked just before the phone went off/ today.

→ My activities ran fluidly and smoothly (= normally) without being blocked just before the phone went off/ today.

Item 13: The right thoughts/movements occurred of their own accord just before the phone went off/ today.

Clarity: This item was not very clear. The term "of their own accord" raised big issues. One participant stated, *"I rule the activity and it does not occur of its own accord"* His suggestion would be to delete this item. Further, the definition of "the right thoughts" is difficult to understand and should be specified. One participant interpreted the "own accord" as being able to move and think without the need of any extra effort. Certainty: the certainty was rated by almost all participants between 60-90% for the EMA and 60-90% for the EDD. Time span: The considered time span included a few minutes to 1 hour for the EMA and the whole day for the EDD except for one student who considered only the last five hours of the day. Assumption: The item applied for everybody except for two chronic pain patient, they only indicated 10 % and 50% for certainty (EMA and EDD). Both suggested the deletion of this item.

Conclusion: Revision may be needed. Suggestions:

→ My movements occurred without the need of any extra effort just before the phone went off/ today.

→ My thoughts occurred without the need of any extra effort just before the phone went off/ today.

→ Deletion of the item

Item 14: The activity I performed just before the phone went off/ today was important.

Clarity: The majority of the participants did not show any issues in understanding this item. Nevertheless, one participant criticized that "important" is difficult to define. To him, it was not clear whether it is asked for the own definition of important, for example valuing a conversation with friends or rather the objective view of importance such as working for the career. Certainty: The certainty was rated by most participants between 90-100% for the

EMA and 90-100% for the EDD. Time span: The considered time span included less than a minute to 1 hour for the EMA and the whole day for the EDD except for one student who considered only the last four hours of the day. Assumption: The item applied for everybody except for one chronic pain patient, he only indicated 50% for certainty (EMA and EDD). Conclusion: No revision.

3.2.3.3 Emotions.

In fact, the following items were very clear: Afraid, Glad, Enthusiastic, Irritated, Happy, Angry, Sad, Proud, and Nervous. The participants did not report any uncertainties about the understanding. However, the emotions Strong and Powerless were lacking in clarity. Strong and Powerless again raised the question of what kind of strong or powerless was asked for. Therefore, it should be specified whether mental or physical strong/powerless is meant. Also, some people were not sure whether powerless means being without energy or without any power to influence something. This should also become clearer by a specification.

Almost all emotions were fine for the domain sensitivity apart from one participant who indicated to feel uncomfortable to rate Afraid, Glad, Sad, and Nervous. Further, nearly all emotions applied. Additionally, one person mentioned that it would be nice to include the emotion *"grateful"* because it is a very important emotion to her.

Conclusion: Revision may be needed. Suggestions:

Just before the phone went off/ today I felt Strong.

→ Just before the phone went off/ today I felt mentally Strong.

Just before the phone went off/ today I felt Powerless.

→ Just before the phone went off/ today I felt mentally Powerless.

3.2.3.4 Response category.

Two different types of scaling were tested to compare the feasibility and preference between the sliding scale and the numerical scale. Most participants agreed on the fact that the sliding scale would be easier and faster to use, and the given answers were described as more intuitive and spontaneously. In contrast, the numerical scale, which the participant reported as being more difficult, would reflect the answer more precisely. To illustrate, one participant stated: *"The numerical scale was more difficult, because you really have to consider precise numbers. It happened for example, that I reconsidered after clicking and I changed my answer to a different number which was not the case for the other scale. So, I was thinking more about it, but it also takes longer to fill it in."* To sum up, 5 out of 6 people preferred the numerical scale because of precision and feasibility. In one participant's opinion, the sliding scale would be more appropriate because *"(…) it describes the emotions better at the moment and the fact to respond more intuitive is better than reasoning too much about it".* One student suggested to combine both scales to use the sliding scale to keep the visual aspect of both poles but still having the numbers below. One further suggestion was to integrate a baseline to have a neutral starting point and then being able to respond in two directions. One participant said: *"It is necessary to have a baseline, so to define the perception of normal to make it possible to refer to normal at the moment when the phone goes off".* A realization of the suggestion can be seen below. The switch position would be located in the middle (0) and can be slid up till +5 or down to -5 (Figure 1).

-5	0	+5
No pain		**Worst possible pain**
Not at all		**Very much**
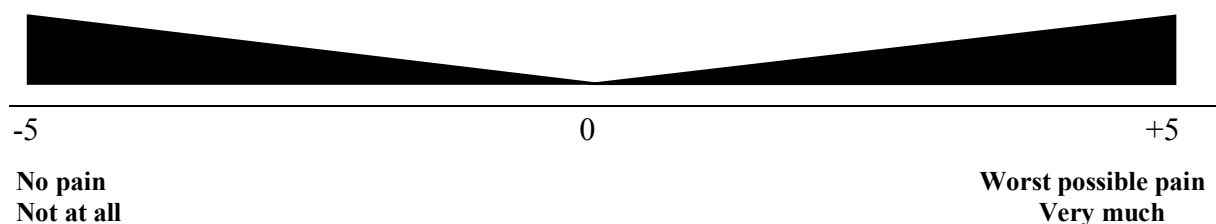
Figure 1. Suggestion for a new scale.

Conclusion

→ Numerical Scale or combination of Numerical and Sliding Scale

3.2.3.5 Other problems.

No item revealed any other problem.

3.2.3.6 Further recommendations.

Further recommendations have been related to two domains. First, the frequency and scope of the diary was criticized. In other words, the diary would be ringing too frequently and would include too many items *"It's too frequent every two hours"*, *"Also, there are too many questions, fewer questions would be better because it takes too long and there is not enough motivation to fill in all questions properly"*. Second, the sound of the alarm was brought up. One participant suggested: *"It would be good to change the sound because it's too aggressive"*.

Conclusion

→ A more discrete ringtone

→ Reduction of the items might be reasonable. Some items could be deleted such as: *"The right thoughts/movements occurred of their own accord just before the phone went off/ today." (Item 13)* because it caused by far the most ambiguity.

→ Regulation of the frequency of the diary entries depends on the utilization of the app: whether it is applied in a research context or for clinical examination.

3.3 Discussion

The results from the CI suggested that most of the items are already clear and do not need any revision. Nevertheless, the interviews identified some issues in clarity for certain items (Item 2, 6, 8, 9, 10, 11, 12,13). Particularly, the items assessing the construct "flow experience" should be refined to reduce or ideally eliminate any kind of ambiguity. The

interpretation of the time frame was quite wide and pointed out that it should be specified, ideally already in the instructions. Therefore, we suggest mentioning in the instructions that a period of 5 min for the EMA and the whole day for the EDD should be considered for the response. Further, the emotions were very clear apart from two items (Item 19: Strong, Item 23: Powerless), which needed the specification "mentally" strong/ powerless. Looking at the response category, the results revealed an explicit preference for the numerical scale. Some participants suggested the transformation of some items into a binary version. We agree that this might make sense for responding conveniently to some questions. However, this transformation would limit the richness of the answers and does not suit most research questions. Further, the dichotomous answers would not be comparable to the interval scaled ones. For this reason, we would not reduce the scaling to a binary one. Also, a new version of a scale was suggested (Figure 1) with the aim to integrate a neutral baseline. For some answers, it would be a really interesting adaption because the starting point of the slider would be placed in the middle (0) with the option for sliding up (+5) and down (-5) according to the perception. This seems to be a very creative reflection and makes sense for some questions such as the emotion items. Nevertheless, this scale would not be applicable for some items e.g. people experiencing DOMS pain. They would not be able to compare their answers to a baseline because they cannot refer to their average pain, since in general they do not have pain at all. Considering this case, (-5) and (0) would become meaningless to them. That is why we would not include this suggestion in the PainDiary. Further, the length of the diary has to be adjusted. One participant stated that the diary would include too many items which is, why he would become tired and bored to fill them in adequately. Consequently, we stress that the scope of the diary should be realistic and not overload the participant. If too many items are included, the attentive completion would decline, which impacts the validation of the data.

The first limitation of the study is the small sample size, which is characteristic of research with CI, but makes it difficult to archive an adequate representation of different demographics and different types of chronic pain. However, we deem it necessary to stress that nevertheless, a quite wide range of variety was present in our demographics. We would even highlight that shedding light on the diversity of nationalities and ethnicity, we worked out a cross-cultural investigation. Nevertheless, for future research, it would be interesting to also include older people and people with fewer years of education since it is known that volunteers tend to be higher in level of education than the average of outcome users (Willis, 2004).

Next, Willis (2004) underlined the importance of being aware that cognitive interviewing is required to detect problems. However, it does not provide a key to adequately fix these problems. Which means for us, that the interview showed us solely the main lacks which have to be addressed. Eventually, we introduced some recommendations targeting the improvement of the items to resolve ambiguities. However, to be sure if the items are indeed better, further investigations are needed. We would suggest a second round of interviews with the refined items to see whether less uncertainty will arise.

In addition, it has been criticized in many studies that the laboratory environment is different from that of the field (Willis, 2004). In our case, the 2-day field testing was part of the procedure which should reduce the bias. Nevertheless, it has to be taken into account that the lab situation in which the interview has been conducted influenced the responses anyhow, but probably less than without the testing phase.

Last, the individuality of each subject has a big impact on the results of the interview. Each participant provided a different perspective, we took particular care to include both, people with acute pain as well as people suffering from chronic pain. Since we are dealing with a little sample size and it is important to consider every remark, each individual

influences the results much stronger than it would be the case in a quantitative approach with bigger samples. However, Willis (2004) stressed that it is not the point to obtain statistical estimation but rather to interview a variety of individuals to achieve a maximized variance.

To conclude, the findings were enriching to get a better understanding of how the items were interpreted and it allowed the detection of problems and implications. Taking into account that that latent phenomena are involved in chronic pain, we still deem that this assessment provided notable findings. This can be helpful to build up valid items which assess what they intend to measure.

4. General Discussion

4.1. Summary

This investigation was meant to identify issues of validity and to offer recommendations for revision and modification of the PainDiary to improve its validity. First, we used the DCV method to provide evidence of validity of the items based on quantitative data. However, this method does not show us why the statistical power of certain items is weak. It solely shows us a lack in content validity for some items which means an overlap in the reflected constructs. Lauwerier et al. (2015) have highlighted the importance of the discriminant validity to distinguish the predictor and the outcome in the analysis. It is constraining to be able to work out theories which have a solid base. If outcome and predictor are not distinctively separable, the research finding would become highly inflated. For this reason, the DCV method revealed information about which items showed major overlaps on several constructs. Nevertheless, this psychometric approach does not determine the source of the uncertainty (Peterson, Peterson, & Powell, 2017).

Second, the addition of the qualitative analysis via the CI leads us to understand why several items are perceived as ambiguous. The CI enabled us to detect issues in the understanding and content coverage and work out suggestions for clarification and improvement. Interestingly, the items which loaded on several constructs in the DCV assessment did not show any bigger problems in clarity via the cognitive interview. This tells us that even if people could imagine several links to more than one construct for the item, the intention of the item was still very clear. In our case, using multiple methods for the assessment illustrates the importance to carefully interpret the results. If we would have only assessed the content validity via the DCV method, the quality of the items would have had appeared less distinct. The combination of both results (DCV and CI) assures us a better integrity from which we conclude that in general, the items of the PainDiary are acceptable.

According to Jobe (2010), the cognitive approach improves the quality of self-reports, however the combination of cognitive and psychometric approaches can be effectively improving the accuracy of data from self-reported instruments. In line with this statement, we conclude that the combined investigation of the PainDairy was an effective and productive way to gather a richness of complimentary data. It helped us to analyze the items from different perspectives and to get a broad picture. From which we conclude that the diary already showed a good content validity which can be improved by applying the recommendations.

4.2 Limitations

However, one participant mentioned that some questions i.e. *"My thoughts/activities ran fluidly and smoothly just before the phone went off."* would have made her aware that she is actually not focused and concentrated very well. She described to notice a sort of "brain fog" which rendered her sad. In line with this statement, diary research has investigated the impact of reactivity (Reynolds, Robles, & Repetti, 2016). Some studies have shown that besides the positive reactivity, also negative reactivity can affect the well-being of the person (Merrilees, Goeke-Morey, & Cummings, 2008). In our opinion, items should be carefully selected to avoid that they trigger too much negative emotions which impacts the patient in a destructive way.

Further, the extensive analyses of the PainDiary does not ensure if the implementation of the yielded suggestions would significantly improve the content validity of the items. Therefore, a second round of cognitive interviews and a repeated DCV investigation would shed light on whether the modifications were successful. In short, this investigation was the first step to identify major weaknesses, however it did not necessarily improve the PainDiary.

4.3 Outlook

For future research, the diary has proven several advantages compared to conventional questionnaires. The investigation has shown that the PainDiary did not show big issues for the memory retrieval. According to Redelmeier and Kahneman (1996), pain questionnaires are often biased by peak pain and pain experience that occur shortly before recall. Our results have shown that most of the participants averaged the day (EDD) to indicate their response. Also, pain fluctuations are evidently better depicted during the course of the day. We conclude that electronic pain diaries are a modern instrument which overcomes certain advantages compared to pain questionnaires and therefore should be further established in pain research. However, the PainDiary has been tested and showed acceptable items. Nevertheless, some items were lacking in clarity and the recommendations should be implemented and tested. For that reason, further investigation is needed to provide evidence for validity.

4.4 Conclusion

The contribution to the development of a valid instrument which assesses good empirical data was the major aim of this investigation. The highlighted need for an adequate measurement of pain was addressed by analyzing the PainDiary. Applying the combination of a quantitative and a qualitative method provided valuable information about the evidence of validity for the PainDiary. The identification of lacks in clarity aims at the prevention of misleading results which could derive from ambiguous items. This investigation offers a solid base to modify certain items in an outcome-orientated way. Further research is needed to apply our suggestions and to validate these modifications to prove increased evidence for validity of the PainDiary.

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Appendices

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APPENDIX A: Flyer Recruitment

VOLUNTEERS NEEDED!

Looking for individuals to participate in cognitive interviews.

This study aims to investigate pain assessment. To examine pain diary items, we would like to conduct cognitive interviews. Furthermore, it will provide recommendations for revision and assess evidence of validity.

To be eligible for the study you must require:

- **Advanced English level (at least C1)**
- **Control Group: University students**
- **Target group: Chronic pain patients**

What do you have to do?

- **The day before the interview:**
  - **15 min strength training (shoulder exercise)**
  - **Fill in 7x during the day a 2min pain diary on a Smartphone**
  - **Fill in 1x end of the day diary (3min)**
- **The day itself:**
  - **1 hour interview at Campus Belval**

Reward: 20 €

Time commitment: approximately 1,5 hour

For further details contact:

E-Mail: charlotte.koeckeritz.001@student.uni.lu

Cognitive Interview
charlotte.koeckeritz.001@student.uni.lu
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Cognitive Interview
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APPENDIX B: Internet Recruitment Posting

Study participants needed: Chronic pain patients for cognitive interview (1h) to examine pain diary items

15.02.18

Université du Luxembourg   Diesen Artikel drucken

Chronic pain patients are needed to help investigate the clarity of items in a pain diary.

Pain diaries filled in by patients are a useful tool for researchers and doctors to investigate all kinds of chronic pain such as lower back pain. Patients record items such as their pain duration, severity and location, any medications they've taken as well as other factors that could be linked to pain such as mood. With this information, doctors and nurses can try to understand what may cause or influence the patients' pain.

The Problem

However, these items can be misunderstood or interpreted in different ways, which can cause biased data. To make sure the items assess exactly what they intend to measure, we, a team of researchers from the University of Luxembourg, would like to conduct cognitive interviews to get a better insight of how patients fill in the items.

The Research Question

Does the pain diary assess what we really want to measure?

Who are we looking for?

Chronic pain patients with an advanced English language level (at least C1 level). Interested participants should contact charlotte.koeckeritz.001@student.uni.lu.

What do participants have to do?

The day before the interview, you will be asked to fill in a 2-min pain diary (7x during the day and 1x on the end of the day). The interview itself will take place on Campus Belval near Esch-sur-Alzette and will last around 1 hour.

We are not collecting personal information about you. Instead, we're first trying out our diary items, so that we can improve them. We'll be asking you about how you come up with your answers and how you are interpreting the questions. Time commitment: approximately 1 hour. To thank you for your participation, you will receive a 20€ voucher.

What is already known?

Chronic pain plays a crucial role in health care, given the fact that one in five people suffer from moderate to severe chronic pain. Pain diaries such as Ecological momentary assessment (EMA) and End of the day diary (EDD) are used to assess chronic pain outside the lab in a daily life context. Previous studies have shown that electronic diary assessment (a smartphone or tablet App) provides a considerable contribution to study pain.

However, certain items in the pain diary are formulated ambiguously for what they intend to measure. Examples are questions such as "How engaged were you in that activity?", which should assess motivation, or "How afraid are you that the pain would worsen?", which intends to measure catastrophizing behavior. These can be misunderstood so it is important to see what people actually report on to build up clear items.

Who will benefit from the study?

15.2.2018 Study participants needed: Chronic pain patients for cognitive interview (1h) to examine pain diary items | www.science.lu

This study aims to investigate pain assessment and will help to advance pain research and potentially improve pain diaries. The cognitive interview will provide recommendations for revision and assess evidence of validity of pain diary items. The results could lead researchers and healthcare practicioners to adjust and improve these items. Ultimately, the study could help to adjust treatment and monitoring of chronic pain patients in the future.

Supervision and Contact

At the University of Luxembourg (research team INSIDE): Supervision by Dr. Dimitri van Ryckeghem. If you are interested we would be glad for your contribution. The recruitment period lasts until 01.04.2018. For further questions or interest in participation, contact Charlotte Köckeritz (email: charlotte.koeckeritz.001@student.uni.lu)

Author: Université du Luxembourg
Editor: Michèle Weber (FNR)
Photo: shotshop.com

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0 Kommentare

Sortieren nach **Älteste**

Kommentar hinzufügen ...

Facebook-Plug-in für Kommentare

APPENDIX C: Information Sheet

UNIVERSITÉ DU
LUXEMBOURG

INFORMATION SHEET

Title of Research Project: The investigation of pain diary items through cognitive interviewing and discriminant content validity

Description of the study:

Thank you very much for your interest in taking part in the current study. Please read this information sheet carefully.

Previous studies have shown that, electronic diary assessment provides a considerable contribution to the study pain. However, studies investigating the content validity of diary items is largely lacking. As such, it is necessary to examine if diary items assess what they intend to measure. In this study, we focus on diary items that are related to pain, fatigue, cognitive and emotional functioning. To address this objective, cognitive interviews (CI) will be conducted to understand better participant's thought process. Hence, this will lead to retain, revise or eliminate items based on the obtained feedback. Finally, this investigation targets recommendations for revision and evidence of validity. Overall, the aim of the study will be the improvement of pain diaries (EMA, EDD). Ultimately, this will contribute to build up valid tools for further pain research or also for applying them in clinical intervention programs.

The interview is expected to last around 1 hour, and you will be given a 20 € gift voucher as compensation for your time and effort.

Participation, data treatment and protection

Your participation is completely voluntary and you may withdraw from the study at any time without consequences. Neither does the project represent a medical examination, nor can it act as a substitute. It, therefore, cannot provide any information on your health status.

All processed data will be stored on password-protected physical drives, to which only authorized researchers working on this project will have access to. All electronic data are pseudonymized from the beginning of data recording. The data collection will be used strictly for research purposes.

Contact person for further questions:
Name: Charlotte Köckeritz; Position: Bachelor student; E-Mail: charlotte.koeckeritz.001@student.uni.lu; +49 151 62945504
Name: Dimitri van Ryckeghem; Position: Postdoctoral researcher; E-Mail: dimitri.vanryckeghem@uni.lu; + 352 466644 9241

APPENDIX D: Participant Informed Consent Form

uni.lu
UNIVERSITÉ DU
LUXEMBOURG

Faculty of Language
and Literature, Humanities,
Arts and Education

RESEARCH PARTICIPANT CONSENT FORM

Title of Research Project: **Investigation of pain diary items through cognitive interviewing and discriminant content validity**

Principal Investigator: Dr. Dimitri van Ryckeghem, Institute for Health and Behaviour,
                                            UR INSIDE University of Luxembourg
Co-Investigator: Charlotte Köckeritz, University of Luxembourg

I _____ (name of participant) have been informed verbally and in writing on the nature of the study, there are no known risks associated with participating in this study.

I have been informed that I am entitled to withdraw my consent at any time without giving reasons and without negative consequences to myself. Furthermore, I can object to a further processing of my data and samples, as well as request these to be deleted.

I agree that data concerning my person collected within the scope of the study are used for scientific purposes only, and are treated as strictly confidential according to the regulations of the Data Protection Act (la loi modifiée du 2 août 2002 sur la protection des données personnelles).

I agree that the interview will be audio-recorded. The recordings will be reviewed by the researchers to gain a full understanding of your experiences.

I have read the information on this form. All of my questions about the study have been answered to my satisfaction. I voluntarily agree to participate in this study.

Date: _____

Participant's Signature:_____

Date: _____

Researcher's Signature: _____

APPENDIX E: Demographic Questionnaire

__ __/__ __/2018

Sociodemographic Form

Please answer the following questions. Complete the blanks or check the boxes next to the category the best describes your situation.

1. Participant Number:_____
2. What is your date of birth? __ __/__ __/__ __ __ __ (mm/ dd/ yyyy)
3. Age _____

4. Gender: □ Male   □ Female
5. Nationality: _____
6. Ethnicity: _____
7. Country of residence: _____
8. Profession/Study Program: _____
9. What is your English level?

   □ Mother tongue
   □ C2 _____ (Certificate)
   □ C1 _____ (Certificate)

10. What is your current relationship status?

    □ Never married
    □ Married
    □ Living with partner in committed relationship
    □ Separated
    □ Divorced
    □ Widowed

11. What is the highest level of education that you completed?

    □ Primary school
    □ High school
    □ Technical-vocational degree
    □ Bachelor degree
    □ Master degree
    □ Postgraduate degree
    Years of education: _____

12. What is your current occupational status?

    □ Homemaker
    □ Unemployed
    □ Retired
    □ On disability
    □ Full-time employed
    □ Part-time employed
    □ Full-time student only
    □ Part-time student only
    □ Other

__ __/__ __/2018

Pain

13. Diagnosis (chronic pain): _____

14. Date of diagnosis *[or duration of experience of chronic pain]*: _____

15. Location: _____

16. Disease or symptom severity: _____

17. Comorbidities: _____

18. Medication: _____

APPENDIX F: Graded Chronic Pain Scale

Graded Chronic Pain Scale

1. On how many days in the last three months have had pain?

PAIN DAYS

___ ___ ___

2. How would you rate your pain on a 0 to 10 scale at the present time, that is right now, where 0 is "no pain" and 10 is "pain as bad as could be"?

										PAIN AS BAD
NO PAIN										COULD BE
0	1	2	3	4	5	6	7	8	9	10

3. In the past three months, how intense was your worst pain rated on a 0 to 10 scale where 0 is "no pain" and 10 is "pain as bad as could be"?

					PAIN AS BAD					
NO PAIN										COULD BE
0	1	2	3	4	5	6	7	8	9	10

4. In the past three months, on the average, how intense was your pain rated on a 0 to 10 scale where 0 is "no pain" and 10 is "pain as bad as could be"? [That is, your usual pain at times you were experiencing pain]
.

										PAIN AS BAD
NO PAIN										COULD BE
0	1	2	3	4	5	6	7	8	9	10

5. About how many days in the last three months have you been kept from your usual activities (work, school or housework) because of pain?

DISABILITY DAYS

___ ___ ___

6. In the past three months, how much has pain interfered with your daily activities rated on a 0 to 10 scale where 0 is "no interference" and 10 is "unable to carry on any activities"?

										UNABLE TO
NO										CARRY ON ANY
INTERFERENCE										ACTIVITIES
0	1	2	3	4	5	6	7	8	9	10

7. In the past three months, how much has pain interfered with your ability to take part in recreational, social and family activities where 0 is "no interference" and 10 is "unable to carry on any activities"?

										UNABLE TO
NO										CARRY ON ANY
INTERFERENCE										ACTIVITIES
0	1	2	3	4	5	6	7	8	9	10

8. In the past three months, how much has pain interfered with your ability to work (including housework) where 0 is "no interference" and 10 is "unable to carry on any activities"?

										UNABLE TO
NO										CARRY ON ANY
INTERFERENCE										ACTIVITIES
0	1	2	3	4	5	6	7	8	9	10

APPENDIX G: DOMS Protocol

DOMS Protocol

Preparations

⇨ have a cell phone ready with clock
⇨ set the shoulder training device with 0kg

When participant enters.

Hi, Can I take your jacket? Ok, as mentioned during the first session we will now do a shoulder strength exercise. During this exercise, you will each time do a set of 5 movements. We will start with doing the movement without any weight. For the movement I will count to 5. You will start the upwards movement when I say start reach the top when I say one and then slowly go down in 4 counts. So, you will reach the lowest point when I say 5. [show the movement in real time]. Try to perform movement with maximal effort. In the beginning this will be easy. It will become harder if weight is added. Try your best to perform the movement with maximal effort. Ok now I will first set your chair [the upper part of the shoulder should be equal to the yellow stripe on the chair]
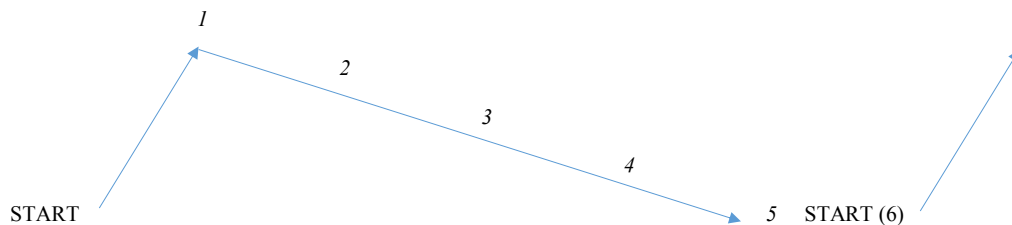
Do this 5 times for each set of (starting from 0 kg).

Ok we will start with the first series. We will do 2 series. Ready. START, 1, 2, 3, 4, 5, START, 1, 2, 3, 4, 5, START, 1, 2, 3, 4, 5, START, 1, 2, 3, 4, 5, START, 1, 2, 3, 4, 5.

⇨ have 45 seconds between each set
⇨ add 5 kg for the next set.
    o Set 1 = 5 x kg
    o Set 2 = 5 x 5kg
    o Set 3 = 5 x 10kg
    o Set 4 = 5 x 15kg
    o Set 5 = 5 x 20 kg
    o Set 6 = 5 x 25kg
    o Set 7 = 5 x 30kg
    o Set 8 = 5 x 35kg
    o Set 9 = 5 x 40kg
    o Set 10 = 5 x 45kg
    o Set 11 = 5 x 50kg

Between each set. Well done! Now I will add some weight. We will do again a set of 5 movements. Try to perform the movement gain with maximal effort.

For the next series again start over again (1.5 minutes rest between both series)

⇨ have 45 seconds between each set
⇨ add 5 kg for the next set.
   o Set 1 = 5 x 0kg
   o Set 2 = 5 x 5kg
   o Set 3 = 5 x 10kg
   o Set 4 = 5 x 15kg
   o Set 5 = 5 x 20 kg
   o Set 6 = 5 x 25kg
   o Set 7 = 5 x 30kg
   o Set 8 = 5 x 35kg
   o Set 9 = 5 x 40kg
   o Set 10 = 5 x 45kg
   o Set 11 = 5 x 50kg

The weight is increased in steps of 5 kg until participants reach the <u>point of volitional fatigue</u> or completes 11 sets. <u>Volitional fatigue is defined as the point at which the participant can no longer control the descent of the weight.</u>

Participants are given verbal encouragement during the contraction (e.g., "Good job" or "Keep going").

At the conclusion of the protocol, participants were asked to abstain from the use of pain or anti-inflammatory medication, unless experiencing significant discomfort.

APPENDIX H: Cognitive Interview Protocol

1

Cognitive Interview Protocol

Date_____ Interview #_____ Interviewer initials_____ Start time of interview _____

Thank you for coming here today to help us test our diary items. At this point, we are not collecting personal information on your life quality. Rather, we show our questions to a few persons in order to improve them. I will read the questions and I would like to hear from you about what you are thinking. Please try to think aloud- just tell me everything that comes to your mind, whether it seems important or not. I will also ask you about how you interpret/understand the question and how you come up with your answer. While doing so, I will take a lot of notes. I will also audiotape this conversation in order to be able to listen to your thoughts and suggestions later on. If any question seems unclear, is hard to answer, or does not make sense, please tell me so. We'll just take our time and probably be ready within an hour. Do you have any question before we start?

Ok, here we go. We will start with the instructions:

Instructions:

EMA: Questionnaire
Please fill out the questionnaire now! Answer the questions about how you felt and what you thought just before the phone went off as honest and accurate as possible.   Click **"Start"** to fill out the questions.

Probes:

- ❖ What is this instruction telling? (Paraphrasing)
- ❖ Are the instructions clear?
- ❖ *What would make the instruction easier to understand?*
- ❖ _____
- ❖ _____
- ❖ _____
- ❖ _____
- ❖ _____
- ❖ _____

EDD: End of the day
The day has ended. To end this day, we would like to ask you to fill out this short questionnaire.   Click **"Start"** to fill out the questions.

Probes:

- ❖ What is this instruction telling? (Paraphrasing)
- ❖ Are the instructions clear?
- ❖ *What would make the instruction easier to understand?*
- ❖ _____
- ❖ _____
- ❖ _____
- ❖ _____
- ❖ _____
- ❖ _____

Ok, well done. Now we will discuss the questions of the diaries you filled out.

2

---

1. How much pain did you experience just before the phone went off/ today? (0 = no pain; 10 = worst possible pain)

- ❖ In general, what difficulties could occur with understanding this item?
- ❖ Can you think of an easier way to word the question?
- ❖ _____
- ❖ _____
- ❖ _____
- ❖ _____

One time frame refers to **"just before the phone went off"**

- ❖ What period did you take into account to answer the question?

One time frame refers to the **"whole day"**

What period did you take into account to answer the question?

- ❖ How sure were you of your answer?

- ❖ Did you think about specific moments?

- ❖ How sure were you of your answer?

	EMA		Notes:	EDD		Notes:
	Yes	No		Yes	No	
Assumption Did the question apply to you?						
Sensitivity Did you feel uncomfortable to talk about it?						
Other Problem Do you see any other problem that you want to mention?						

---

2. How fatigued did you feel just before the phone went off/today? (0 = no fatigue; 10 = worst possible fatigue)

- ❖ In general, what difficulties could occur with understanding this item?
- ❖ Can you think of an easier way to word the question?
- ❖ _____
- ❖ _____
- ❖ _____
- ❖ _____

One time frame refers to **"just before the phone went off"**

- ❖ What period did you take into account to answer the question?

One time frame refers to the **"whole day"**

What period did you take into account to answer the question?

- ❖ How sure were you of your answer?

- ❖ Did you think about specific moments?

- ❖ How sure were you of your answer?
- ❖ _____

3

	EMA		Notes:	EDD		Notes:
	Yes	No		Yes	No	
Assumption Did the question apply to you?						
Sensitivity Did you feel uncomfortable to talk about it?						
Other Problem Do you see any other problem that you want to mention?						

---

3. How much did your pain bother you just before the phone went off/today? (0 = not at all; 10 = very much)

- ❖ In general, what difficulties could occur with understanding this item?
- ❖ Can you think of an easier way to word the question?
- ❖ _____
- ❖ _____
- ❖ _____

One time frame refers to **"just before the phone went off"**

- ❖ What period did you take into account to answer the question?
  [_____]

- ❖ How sure were you of your answer?
  _____

One time frame refers to the **"whole day"**

What period did you take into account to answer the question?
[_____]

- ❖ Did you think about specific moments?

- ❖ How sure were you of your answer?
  _____

	EMA		Notes:	EDD		Notes:
	Yes	No		Yes	No	
Assumption Did the question apply to you?						
Sensitivity Did you feel uncomfortable to talk about it?						
Other Problem Do you see any other problem that you want to mention?						

---

4. How much did your pain interfere with your activities just before the phone went off/ today? (0 = not at all; 10 = very much)

- ❖ In general, what difficulties could occur with understanding this item?
- ❖ Can you think of an easier way to word the question?
- ❖ _____
- ❖ _____
- ❖ _____

One time frame refers to **"just before the phone went off"**

- ❖ What period did you take into account to answer the question?
  [_____]

- ❖ How sure were you of your answer?
  _____

One time frame refers to the **"whole day"**

What period did you take into account to answer the question?
[_____]

- ❖ Did you think about specific moments?
  _____

4

❖ How sure were you of your answer?

_____

	EMA		Notes:	EDD		Notes:
	Yes	No		Yes	No	
Assumption Did the question apply to you?						
Sensitivity Did you feel uncomfortable to talk about it?						
Other Problem Do you see any other problem that you want to mention?						

5. How much did your pain draw your attention just before the phone went off/ today? (0 = not at all; 10= very much)

❖ In general, what difficulties could occur with understanding this item?
❖ Can you think of an easier way to word the question?
❖
❖ _____
❖ _____
❖ _____

One time frame refers to **"just before the phone went off"**

❖ What period did you take into account to answer the question?

[   ]

❖ How sure were you of your answer?

_____

One time frame refers to the **"whole day"**

What period did you take into account to answer the question?

[   ]

❖ Did you think about specific moments?

❖ How sure were you of your answer?

_____

	EMA		Notes:	EDD		Notes:
	Yes	No		Yes	No	
Assumption Did the question apply to you?						
Sensitivity Did you feel uncomfortable to talk about it?						
Other Problem Do you see any other problem that you want to mention?						

5

6. How much did you avoid movements that cause pain today? (0 = not at all; 10= very much)

One time frame refers to the **"whole day"**

❖ What period did you take into account to answer the question?

❖ Did you think about specific moments?

❖ How sure were you of your answer?

	EMA		Notes:	EDD		Notes:
	Yes	No		Yes	No	
Assumption Did the question apply to you?						
Sensitivity Did you feel uncomfortable to talk about it?						
Other Problem Do you see any other problem that you want to mention?						

❖ In general, what difficulties could occur with understanding this item?
❖ Can you think of an easier way to word the question?
❖
❖
❖
❖

7. How much did you worry about your pain just before the phone went off/today? (0 = not at all; 10= very much)

❖ In general, what difficulties could occur with understanding this item?
❖ Can you think of an easier way to word the question?
❖
❖
❖
❖

One time frame refers to **"just before the phone went off"**

❖ What period did you take into account to answer the question?

❖ How sure were you of your answer?

One time frame refers to the **"whole day"**

What period did you take into account to answer the question?

❖ Did you think about specific moments?

❖ How sure were you of your answer?

6

	EMA		Notes:	EDD		Notes:
	Yes	No		Yes	No	
Assumption Did the question apply to you?						
Sensitivity Did you feel uncomfortable to talk about it?						
Other Problem Do you see any other problem that you want to mention?						

8. How afraid were you that your shoulder pain would worsen just before the phone went off/today? (0 = not at all; 10= very much)

- ❖ In general, what difficulties could occur with understanding this item?
- ❖ Can you think of an easier way to word the question?
- ❖
- ❖
- ❖
- ❖

One time frame refers to **"just before the phone went off"**

- ❖ What period did you take into account to answer the question?

- ❖ How sure were you of your answer?

One time frame refers to the **"whole day"**

- ❖ What period did you take into account to answer the question?

- ❖ Did you think about specific moments?

- ❖ How sure were you of your answer?

	EMA		Notes:	EDD		Notes:
	Yes	No		Yes	No	
Assumption Did the question apply to you?						
Sensitivity Did you feel uncomfortable to talk about it?						
Other Problem Do you see any other problem that you want to mention?						

9. How much were you engaged in the activity/ies you performed just before the phone went off/ today? (0 =not at all; 10= very much)

- ❖ In general, what difficulties could occur with understanding this item?
- ❖ Can you think of an easier way to word the question?
- ❖
- ❖
- ❖
- ❖

7

One time frame refers to **"just before the phone went off"**

- ❖ What period did you take into account to answer the question?

- ❖ How sure were you of your answer?

One time frame refers to the **"whole day"**

What period did you take into account to answer the question?

- ❖ Did you think about specific moments?

- ❖ How sure were you of your answer?

	EMA		Notes:	EDD		Notes:
	Yes	No		Yes	No	
Assumption Did the question apply to you?						
Sensitivity Did you feel uncomfortable to talk about it?						
Other Problem Do you see any other problem that you want to mention?						

10. I felt just the right amount of challenge in the activity I performed just before the phone went off/ today. (0 =not at all; 10= very much)

- ❖ In general, what difficulties could occur with understanding this item?
- ❖ Can you think of an easier way to word the question?
- ❖
- ❖
- ❖
- ❖

One time frame refers to **"just before the phone went off"**

- ❖ What period did you take into account to answer the question?

- ❖ How sure were you of your answer?

One time frame refers to the **"whole day"**

- ❖ What period did you take into account to answer the question?

- ❖ Did you think about specific moments?

- ❖ How sure were you of your answer?

	EMA		Notes:	EDD		Notes:
	Yes	No		Yes	No	
Assumption Did the question apply to you?						
Sensitivity Did you feel uncomfortable to talk about it?						
Other Problem Do you see any other problem that you want to mention?						

8

11. I felt totally absorbed in the activity I was doing just before the phone went off/ today. (0 =not at all; 10= very much)

- ❖ In general, what difficulties could occur with understanding this item?
- ❖ Can you think of an easier way to word the question?
- ❖ _____
- ❖ _____
- ❖ _____

One time frame refers to **"just before the phone went off"**   One time frame refers to the **"whole day"**

- ❖ What period did you take into account to answer
  the question?
  [_____]

- ❖ How sure were you of your answer?

- ❖ What period did you take into account to answer
  the question?
  [_____]

- ❖ Did you think about specific moments?

- ❖ How sure were you of your answer?
  _____

	EMA		Notes:	EDD		Notes:
	Yes	No		Yes	No	
Assumption Did the question apply to you?						
Sensitivity Did you feel uncomfortable to talk about it?						
Other Problem Do you see any other problem that you want to mention?						

12. My thoughts/activities ran fluidly and smoothly just before the phone went off/today. (0 =not at all; 10= very much)

- ❖ In general, what difficulties could occur with understanding this item?
- ❖ Can you think of an easier way to word the question?
- ❖ _____
- ❖ _____
- ❖ _____

One time frame refers to **"just before the phone went off"**   One time frame refers to the **"whole day"**

- ❖ What period did you take into account to answer
  the question?
  [_____]

- ❖ How sure were you of your answer?
  _____

- ❖ What period did you take into account to answer
  the question?
  [_____]

- ❖ Did you think about specific moments?

- ❖ How sure were you of your answer?
  _____

9

	EMA		Notes:	EDD		Notes:
	Yes	No		Yes	No	
Assumption Did the question apply to you?						
Sensitivity Did you feel uncomfortable to talk about it?						
Other Problem Do you see any other problem that you want to mention?						

13. The right thoughts/movements occurred of their own accord just before the phone went off/today. (0 =not at all; 10= very much)

- ❖ In general, what difficulties could occur with understanding this item?
- ❖ Can you think of an easier way to word the question?
- ❖
- ❖
- ❖

One time frame refers to **"just before the phone went off"**

- ❖ What period did you take into account to answer the question?

- ❖ How sure were you of your answer?

One time frame refers to the **"whole day"**

- ❖ What period did you take into account to answer the question?

- ❖ Did you think about specific moments?

- ❖ How sure were you of your answer

	EMA		Notes:	EDD		Notes:
	Yes	No		Yes	No	
Assumption Did the question apply to you?						
Sensitivity Did you feel uncomfortable to talk about it?						
Other Problem Do you see any other problem that you want to mention?						

14. The activity/ies I performed just before the phone went off/today was/were important. (0 =not at all; 10= very much)

- ❖ In general, what difficulties could occur with understanding this item?
- ❖ Can you think of an easier way to word the question?
- ❖
- ❖
- ❖

10

One time frame refers to **"just before the phone went off"**

❖ What period did you take into account to answer the question?

[   ]

One time frame refers to the **"whole day"**

❖ How sure were you of your answer?

_____

❖ What period did you take into account to answer the question?

[   ]

❖ Did you think about specific moments?

_____

❖ How sure were you of your answe

	EMA		Notes:	EDD		Notes:
	Yes	No		Yes	No	
Assumption Did the question apply to you?						
Sensitivity Did you feel uncomfortable to talk about it?						
Other Problem Do you see any other problem that you want to mention?						

11

| 15. Today/ Just before the phone went off, I felt **Afraid**? (0 = totally disagree; 10 = totally agree) |

	EMA		EDD		Notes:
	Yes	No	Yes	No	
Understanding Do you think this emotion is clear to most people?					
Assumption Did the question apply to you?					
Sensitivity Did you feel uncomfortable to talk about?					
Other Problem Do you see any other problem that you want to mention?					

| 16. Today/ Just before the phone went off, I felt **Glad**? (0 = totally disagree; 10 = totally agree) |

	EMA		EDD		Notes:
	Yes	No	Yes	No	
Understanding Do you think this emotion is clear to most people?					
Assumption Did the question apply to you?					
Sensitivity Did you feel uncomfortable to talk about?					
Other Problem Do you see any other problem that you want to mention?					

| 17. Today/ Just before the phone went off, I felt **Enthusiastic**? (0 = totally disagree; 10 = totally agree) |

	EMA		EDD		Notes:
	Yes	No	Yes	No	
Understanding Do you think this emotion is clear to most people?					
Assumption Did the question apply to you?					
Sensitivity Did you feel uncomfortable to talk about?					
Other Problem Do you see any other problem that you want to mention?					

| 18. Today/ Just before the phone went off, I felt **Irritated**? (0 = totally disagree; 10 = totally agree) |

	EMA		EDD		Notes:
	Yes	No	Yes	No	
Understanding Do you think this emotion is clear to most people?					
Assumption Did the question apply to you?					
Sensitivity Did you feel uncomfortable to talk about?					

12

Other Problem Do you see any other problem that you want to mention?					

19. Today/ Just before the phone went off, I felt **Happy**? (0 = totally disagree; 10 = totally agree)

	EMA		EDD		Notes:
	Yes	No	Yes	No	
Understanding Do you think this emotion is clear to most people?					
Assumption Did the question apply to you?					
Sensitivity Did you feel uncomfortable to talk about?					
Other Problem Do you see any other problem that you want to mention?					

20. Today/ Just before the phone went off, I felt **Angry**? (0 = totally disagree; 10 = totally agree)

	EMA		EDD		Notes:
	Yes	No	Yes	No	
Understanding Do you think this emotion is clear to most people?					
Assumption Did the question apply to you?					
Sensitivity Did you feel uncomfortable to talk about?					
Other Problem Do you see any other problem that you want to mention?					

21. Today/ Just before the phone went off, I felt **Powerless**? (0 = totally disagree; 10 = totally agree)

	EMA		EDD		Notes:
	Yes	No	Yes	No	
Understanding Do you think this emotion is clear to most people?					
Assumption Did the question apply to you?					
Sensitivity Did you feel uncomfortable to talk about?					
Other Problem Do you see any other problem that you want to mention?					

22. Today/ Just before the phone went off, I felt **Relaxed**? (0 = totally disagree; 10 = totally agree)

13

	EMA		EDD		Notes:
	Yes	No	Yes	No	
Understanding Do you think this emotion is clear to most people?					
Assumption Did the question apply to you?					
Sensitivity Did you feel uncomfortable to talk about?					
Other Problem Do you see any other problem that you want to mention?					

23. Today/ Just before the phone went off, I felt **Strong**? (0 = totally disagree; 10 = totally agree)

	EMA		EDD		Notes:
	Yes	No	Yes	No	
Understanding Do you think this emotion is clear to most people?					
Assumption Did the question apply to you?					
Sensitivity Did you feel uncomfortable to talk about?					
Other Problem Do you see any other problem that you want to mention?					

24. Today/ Just before the phone went off, I felt **Sad**? (0 = totally disagree; 10 = totally agree)

	EMA		EDD		Notes:
	Yes	No	Yes	No	
Understanding Do you think this emotion is clear to most people?					
Assumption Did the question apply to you?					
Sensitivity Did you feel uncomfortable to talk about?					
Other Problem Do you see any other problem that you want to mention?					

25. Today/ Just before the phone went off, I felt **Proud**? (0 = totally disagree; 10 = totally agree)

	EMA		EDD		Notes:
	Yes	No	Yes	No	
Understanding Do you think this emotion is clear to most people?					
Assumption Did the question apply to you?					
Sensitivity Did you feel uncomfortable to talk about?					
Other Problem Do you see any other problem that you want to mention?					

26. Today/ Just before the phone went off, I felt **Nervous**? (0 = totally disagree; 10 = totally agree)

14

	EMA		EDD		Notes:
	Yes	No	Yes	No	
Understanding Do you think this emotion is clear to most people?					
Assumption Did the question apply to you?					
Sensitivity Did you feel uncomfortable to talk about?					
Other Problem Do you see any other problem that you want to mention?					

Response Category

You were used to test the items with two different kinds of scales. I will first ask you some questions regarding the sliding scale (0-10):

Scale 1

0	?	10

no pain   worst possible pain

Probes:

- ❖ How easy or difficult was it to choose an answer?
- ❖ Are there any confusing things on this pain scales?
- ❖ _____
- ❖ _____
- ❖ _____
- ❖ _____
- ❖ _____
- ❖ _____
- ❖ _____
- ❖ _____
- ❖ _____

Now the numerical scale (0-10)

Scale 2

0	1	2	3	4	5	6	7	8	9	10

no pain   worst possible pain

Probes:

- ❖ How easy or difficult was it to choose an answer?
- ❖ What do the numbers on the scale mean to you?
- ❖ Are there any confusing things on this pain scales?
- ❖ _____
- ❖ _____
- ❖ _____

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- ❖ _____
- ❖ Which pain scale do you prefer? Why?
- ❖ _____
- ❖ _____
- ❖ _____
- ❖ _____
- ❖ _____

Probe:

- ❖ Is there anything else that you would like to suggest that would help us to improve these items for future use?
- ❖ _____
- ❖ _____
- ❖ _____

These are all the questions I have for you. Do you have any other comments about your experience that you would like to share with me?

Your comments were very helpful. Thank you very much for your time.

APPENDIX I: Receipt for Gift Vouchers

Receipt

I participated in the research study "The investigation of pain diary items via cognitive interviewing" and I got rewarded 20€ in the form of SODEXO- vouchers.

Name, Surname: _____

Street, Number: _____

Zip code, Town: _____

Nº Voucher 1 _____
Nº Voucher 2 _____

Esch-sur Alzette,

_____
Signature Participant

_____
Signature Interviewer

Contact person:
Name: Charlotte Köckeritz; Position: Bachelor student; E-Mail: charlotte.koeckeritz.001@student.uni.lu +49 151 62945504
Name: Dimitri van Ryckeghem; Position: Postdoctoral researcher; E-Mail: Dimitri.vanryckeghem@uni.lu + 352 466644 9241

Bachelor
Académique
en
Psychologie

BAP

Erklärung zur Autorenschaft

Hiermit versichere ich, dass ich die Bachelorarbeit mit dem Titel:

Content analyses of a pain diary

A Qualitative and Quantitative Investigation via Cognitive Interviewing and Discriminant

Content Analysis

selbstständig verfasst und keine anderen als die angegebenen Quellen und Hilfsmittel benutzt habe. Alle aus fremden Quellen direkt oder indirekt übernommenen Gedanken habe ich als solche kenntlich gemacht.

Ort und Datum

Belval, July 1, 2018

Name und Unterschrift

Charlotte Köckeritz

C. Köckeritz

UNIVERSITÉ DU
LUXEMBOURG