MASTER THESIS

The development of a protocol for integrating biocueing with the Sense-IT application in alcohol addiction treatment.

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30 ECTS

19-08-2020

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Tactus verslavingszorg

Abstract

Background: Clients suffering from Alcohol Use Disorder (AUD) often have difficulty staying aware and regulating their emotions. In order to increase awareness on craving, physiological arousal and stress, which is assumed to be related to relapse, it might be of interest to offer additional physiological monitoring and feedback to existing treatment. Sense-IT is an ambulatory biofeedback application that aims to increase awareness on the physiological processes elicited by arousal, emotions and cravings. Physiological aspects are not yet included in the existing addiction treatment program, which is mainly focused on cognition, suggesting integrating Sense-IT could add innovative aspects to the treatment program. Objective: In the current research, a protocol has been iteratively designed that would support the optimal implementation of the Sense-IT in the regular inpatient addiction treatment at Tactus, a Dutch healthcare organisation focused on addiction treatment. Methods: For this qualitative study, the protocol was designed using User Centred Design (UCD) in the existing Element-Method-Product- framework for developing prototypes as is in line with the methods used by the designers of Sense-IT. The current study was divided into two main cycles, one focused on professionals and one on clients. Within these cycles, three steps were created in order to design the protocol. The first step was conducting individual semi-structured interviews with five professionals based on which the concept version of the protocol was created. This version was presented for feedback to the professionals and a detailed version was constructed. The final step was to test the detailed version in a pilot with client of the inpatient addiction department within Tactus in order to come to the revised version of the protocol after evaluation of the detailed version. Results: The results show that Sense-IT can be integrated in the form of an intervention where a training with cravings, elicited by cue exposure, is offered in order to increase awareness of physiological processes during the experience of cravings or arousal induced by other factors. A complete and useful protocol was designed including all details, example questions and rationale regarding the intervention and can function as a manual for the executive therapist when offering the sessions. Conclusion: It was found that Sense-IT indeed could offer support in learning to recognise cravings, which implies that the main goal of integrating Sense-IT can be met when the designed protocol is applied. The revised version of the Sense-IT protocol is generally ready for further uptake and analysis showed that the applied research design is in line with existing approaches of integrating eHealth innovations into the existing treatment. The only

barriers that stand in the way of integration are the limited resources within Tactus as evidenced by the fact that the researcher conducted the pilot. Recommended for Tactus is to look further into this issue and its possible solutions. For future research long term effectivity can be examined. it can be tested how this can be extended into the ambulatory treatment. Also, it can be tested how this can be extended into the ambulatory treatment, since it was estimated by the clients that the benefits would even be more significant in an ambulatory setting. Finally, for Tactus it is recommended to have an ambassador take the lead for further implementation of Sense-IT.

Keywords: Protocol design, Addiction treatment, Sense-IT, Ambulatory biofeedback, Biocueing.

The development of a protocol for integrating biocueing with the Sense-IT application in alcohol addiction treatment.

In the Netherlands, 75.4% out of all people above the age of 12 is classified as a drinker, out of which 10.5% drinks excessively (Centraal bureau voor de Statistiek, 2020). Here, excessive drinking implies the consumption of over 14 units a week for women and over 21 for men. 10.8 % of all drinkers is categorised as a binge drinker who consumes over 6 units (men) and over 4 units (women) in one day at least once a week. It is found that 12.2 % of the men are drinking excessively compared to 8.7 % of the women. Consuming excessive amounts of alcohol could lead to alcohol-related problems, e.g. violent behaviour, depression, several health issues, such as coronary heart disease and breast cancer, and family and other social problems (Hunt, Malhi, Lai, & Cleary, 2020; Room, Babor, & Rehm, 2005). Alcohol addiction can be a result of a set of variables, such as, social environment, socioeconomic status and psychological distress (Calling, Ohlsson, Sundquist, Sundquist, & Kendler, 2019; Cambron et al., 2017). Also people with a particular set of genetic factors are more vulnerable to developing AUD (Edenberg & Foroud, 2013; Tawa, Hall, & Lohoff, 2016).

Alcohol Addiction

In addiction treatment, patients with alcohol problems are diagnosed in accordance to the DSM- 5 criteria of alcohol use disorder (AUD) (American Psychiatric Association, 2013). AUD consists of a mild, moderate and severe sub-classification, which are determined by the amount of symptoms. Symptoms that are experienced most often are craving, the amount or duration of drinking and dependency. Cravings are defined as an intense urge to use the substance, in this alcohol (Stewart & Paulus, 2013). Often this is paired with a perceived extreme emotional feelings with regards to alcohol. Cravings are one of the main predictors for relapse (de Haan, van der Palen, Wijdeveld, Buitelaar, & De Jong, 2014; Sinha, 2011).

AUD is likely to be associated with difficulties in emotion regulation, e.g. using suppression or rumination, which are factors that are also associated with craving (Cavicchioli, Movalli, & Maffei, 2019; Eddie, Kim, Lehrer, Deneke, & Bates, 2014; Mikolajczak, Petrides, & Hurry, 2009; Rakesh, Prachi, & Akanksha, 2011). Difficulties in emotion regulation is a crucial factor for maintaining AUD among some clients, suggesting that AUD will not be treated effectively for those clients if the difficulties in emotion regulation are not incorporated in the treatment plan (Berking et al., 2011; Petit et al., 2015). Difficulties in emotion regulation can be distributed into six dimensions (Gratz & Roemer, 2004). The most dominant dimension for clients with AUD is the reduced level of emotional awareness. Emotional awareness is the ability to recognise and identify emotions, including

both thoughts and feelings as well as physiological sensations (Derks, Visser, Bohlmeijer, & Noordzij, 2017). Low levels of emotional awareness can be referred to as alexithymia (de Haan, van der Palen, Wijdeveld, Buitelaar, & De Jong, 2014; Subic-Wrana et al., 2014). People suffering from alexithymia experience a challenge in processing emotions, where the distinction between feelings and bodily sensations, e.g. cravings, distress and negative affect, is difficult (Rohsenow & Monti, 1999; Subic-Wrana, Beutel, Knebel, & Lane, 2010; van Lier et al., 2018). However, emotional awareness is crucial to identify cravings in high-risk situations. Early identification provides the client with more opportunity to act upon the cravings and to prevent relapse in an affective peak during risky situations (van Lier et al., 2017). Therefore, it is of high relevance to include emotional awareness actively into the therapeutic protocol in order to make alcohol addiction treatment more effective in such a way that bodily sensations can be recognised in order to deal with cravings and to facilitate coping resources (Bochand & Nandrino, 2010; Rohsenow & Monti, 1999).

At this moment, inpatient clinical alcohol addiction treatment generally starts with a detox period, where professionals offer support, guidance and medical treatment. Generally, this period of detoxification is characterised by several withdrawal symptoms, e.g. stress, depression-, and anxiety- related symptoms, that could lead to cravings. The symptoms may differ in severity and can affect the mental state of the client, which explains the thorough guidance by professionals. Following the detox period, generally Cognitive Behavioural Therapy (CBT) and Motivational Interviewing (MI) are prescribed by the Dutch GGZ standards (AKWA GGZ, 2020).

Unfortunately, physiological processes have received less attention in the field of AUD treatment. However, research has indicated that clients with alcohol related problems show a heightened physiological response during the period of withdrawal in heart rate that is elicited by the sympathetic nervous system, which implies higher states of arousal (van Lier et al., 2017). Therefore, it is interesting to study whether heart rate could be measured to analyse arousal and aid in momentary emotional awareness in order to allow for a better identification of craving and thereby possibly prevent relapse. Research has suggested that this can possibly be done by including ambulatory biofeedback into therapy and to expand therapy into a real-world setting (Derks, Visser, Bohlmeijer, & Noordzij, 2017; Derks, Klaassen, Westerhof, Bohlmeijer, & Noordzij, 2019).

The current research focuses on the implementation of ambulatory biofeedback for AUD clients aiming to enhance emotional awareness. Research has found that the implementation of eHealth, such as a technological tool used for ambulatory biofeedback,

requires a different protocol or approach compared to regular face to face therapy (Buis, 2019; van Dooren, Visch, Spijkerman, Goossens, & Hendriks, 2020). In addition, research has indicated that a science based protocol will facilitate the uptake of new technological tools (LaMonica et al., 2019). So, in order to facilitate an effective adoption of the mental eHealth application, a proper protocol should be developed taking into account the existing clinical practice.

Bio cueing

Biofeedback is the technical name for a bio-mirror that provides people with feedback of physiological variables, e.g. heart rate, obtained with real-time measurements (Yu, 2018). It is a technique that is linked to the enhancement of self- awareness and self- regulation by turning unconscious bodily processes, such as arousal and stress, into conscious control (Brown, 1977; Yu, 2018). The effectiveness of biofeedback in the clinical field depends on several factors, namely the user's perception, understanding and usage of the feedback. Biofeedback can have several different forms of providing the user with biological cues or signals, e.g. sensory, visual and haptic cues, that will function as a warning for the user in risky situations. This way of providing the user with individualised biofeedback in daily life is called ambulatory biofeedback or bio cueing (ter Harmsel et al., n.d.). Ambulatory biofeedback can be also explained as a feedback loop consisting of three processes, (1) Obtaining awareness of the physiological responses and connecting that to unconscious emotional, behavioural and cognitive states, (2) retrieving skills on how to control that response, (3) implementing that control of response into daily life (Yu, 2018). This specific research will be mainly focused on the first process. Biofeedback in general has found to have a positive effect on well-being and performance in clinical settings (Crockett, Gill, Cashwell, & Myers, 2017). In addition, besides the fact that it is cost-effective, it was proven that biofeedback offers the ability to teach self- regulation, which is crucial for clients with AUD (Austad & Gendron, 2018). Furthermore, biofeedback might be useful for a reduction of perceived anxiety through heart rate control (Gatchel & Proctor, 1976; Penzlin, Siepmann, Illigens, Weidner, & Siepmann, 2015). In addition, it was found to be helpful in the reduction of cravings in all substance use disorders (SUD) including AUD (Eddie, Kim, Lehrer, Deneke, & Bates, 2014). This research found that participants receiving biofeedback from a handheld EmWave device in addition to the inpatient treatment as usual (TAU) showed a reduction in cravings compared to the participants only receiving TAU. Over the course of three weeks, the first group participated in two daily sessions of 20 minutes where they used the biofeedback device on their own. In addition, they were asked to utilise the techniques

they had learned whenever they experienced cravings outside their sessions. Thus, for the sake of preventing relapse in clients with AUD, cravings could be more controlled. Therefore, bio cueing aimed at heart rate could be tested in addition to the regular inpatient alcohol addiction treatment.

Technology in AUD Treatment

Multiple studies have been discovering the options of including technology into AUD treatment and mental health care. For instance, it was found that the adoption of mobile app in AUD treatment is effective when striving for a reduction in alcohol consumption (Sawares, Shen, Xue, Abi-Jaoude, & Wiljer, 2017). Also, many studies show positive results in behavioural, cognitive and physiological indicators of mental health (Song, Qian, & Yu, 2019). These findings are promising and imply that the integration of an ambulatory biofeedback system to increase emotional awareness, on a cognitive levels as well as on a physiological level, has potential that should be researched.

AUD at Tactus Verslavingszorg

The current research was conducted within the inpatient department at Tactus, addiction care in the Netherlands, where both the professionals as the clients were recruited. Tactus is a Dutch organisation tailored to addiction treatment, which can be conducted in multiple forms. Ambulatory and inpatient treatments are offered on an individual level as well as within a group. The current research focuses on the inpatient treatment. The treatment program that is leading in the inpatient treatment at Tactus is ‘Verslaving de Baas’. This program consists of eleven group sessions of which the content is predetermined in the designated manual. The sessions are offered continuously and clients join the program regardless of the session whenever they start until all sessions are attended. The first step of the regular inpatient treatment is a detox phase, which will take approximately four – eight days after which the client will be included in clinical inpatient treatment based on the ‘Verslaving de Baas’ program. In this program a strict weekly schedule is utilised. On a daily basis, clients are given time to write in their diary and reflect. Furthermore, once a week a psychoeducation session will be given. On the other weekdays different group therapy sessions are offered, such as psychomotor therapy (PMT). These are based on cognitive behavioural therapy (CBT) and motivational interviewing (MI) as the Dutch GGZ standards prescribe (AKWA GGZ, 2020). However, therapy focused on emotional awareness using technology is not used yet in clinical alcohol addiction treatment and therefore it was requested by Tactus to analyse possibilities in order to do so.

Technology at Tactus

Within Tactus, many new eHealth technologies have been adopted recently, such as virtual reality for tobacco addiction, but also apps, internet based interventions and sensor-technologies for AUD treatment. An example of the latter is the Empatica E4 wearable, which was recently tested in order to identify cravings within this client population. However, mostly of the average physiological data concerning heart rate, cardiovascular activity and electrodermal activity was tracked on a longer period of time (van Lier et al., 2017; van Lier et al., 2019). Based on costs and the finding that sudden, shorter periods of arousal were not measured properly with the Empatica E4, Sense-IT was recommended to be a proper alternative to test in this field. Therefore, Tactus requested research into integrating this technological tool into the regular alcohol addiction treatment by means of developing a tailored protocol.

Sense-IT Application

An ambulant biofeedback or bio cueing system that can be used in the clinical field in order to increase the level of emotional awareness by providing the user information concerning their heart rate, is the Sense-IT[1] (Derks, Visser, Bohlmeijer, & Noordzij, 2017). The aim of Sense-IT is to support users in obtaining understanding of the changes in their emotional and physiological arousal and support affect recognition in order to not only increase emotional awareness, but also (re) gain autonomy, maximise self-determination and to create the possibility to intervene in time. Sense-IT is a biosensor that is based on ambulatory e-coaching where the same application is downloaded on a smartphone and smartwatch or wearable and will be synchronised via Bluetooth (Derks, Klaassen, Westerhof, Bohlmeijer, & Noordzij, 2019). This smartwatch is designed with an integrated heart rate sensor, referred to as a photoplethysmography (PPG), which functions based on the intensity of infrared signals that indicate the blood volume pulse, which is considered to be a good approximation of heart rate (Saquib, Papon, Ahmad, & Rahman, 2015; Tamura, Maeda, Sekine, & Yoshida, 2014). Personalised, haptic cues are send by means of vibrations from the smartwatch when higher levels of heart rate are measured. Visual cues are offered as well in the form of an exclamation mark on the screen of the smartwatch. One consideration of using Sense-IT to measure heart rate is that the sensor does not distinguish between physical or mental arousal. The explanation for the differences in heart rate are not necessarily linked to physical exertion in case of physical arousal, but will also provide an indication of

[1] The Sense-IT app is developed by Scelta, Universiteit Twente, VUmc and Arkin.

psychological activation and mental arousal, also called the Psychological Correlate of Emotional Arousal (PCEA) (Derks, Visser, Bohlmeijer, & Noordzij, 2017; Yang, Jia, Liu, & Sun, 2017) . However, this is tackled by adding a function to rate the arousal level on a scale from 0 – 10 with the possibility to add notes. So far, Sense-IT has been designed using a User Centered Design (UCD) and User Experience (UX) in the sector of borderline personality disorder (BPD) at GGNet Scelta, Apeldoorn, where the main target of Sense-IT was to increase emotional awareness (Derks, Klaassen, Westerhof, Bohlmeijer, & Noordzij, 2019). UCD is an approach designed by Norman (1986) in which end-users are included in the design process in order to tailor the product to the user their needs. During this research it was experienced that the clients as well as the therapists were quite enthusiastic about using Sense-IT, whereas those groups are known to be rather reluctant when it comes to implementing technological innovations. In fact, the main advantage that these participants reported is the added value of taking the therapy sessions out of that context and implementing a part into their daily lives.

Sense-IT was designed using the CeHRes Roadmap (van Gemert-Pijnen et al., 2011). At the time of this research, a prototype was created and is available for the operationalisation phase as is presented in the roadmap in Figure 1. In order to initiate the implementation, research needs to enlighten how this can be done best.

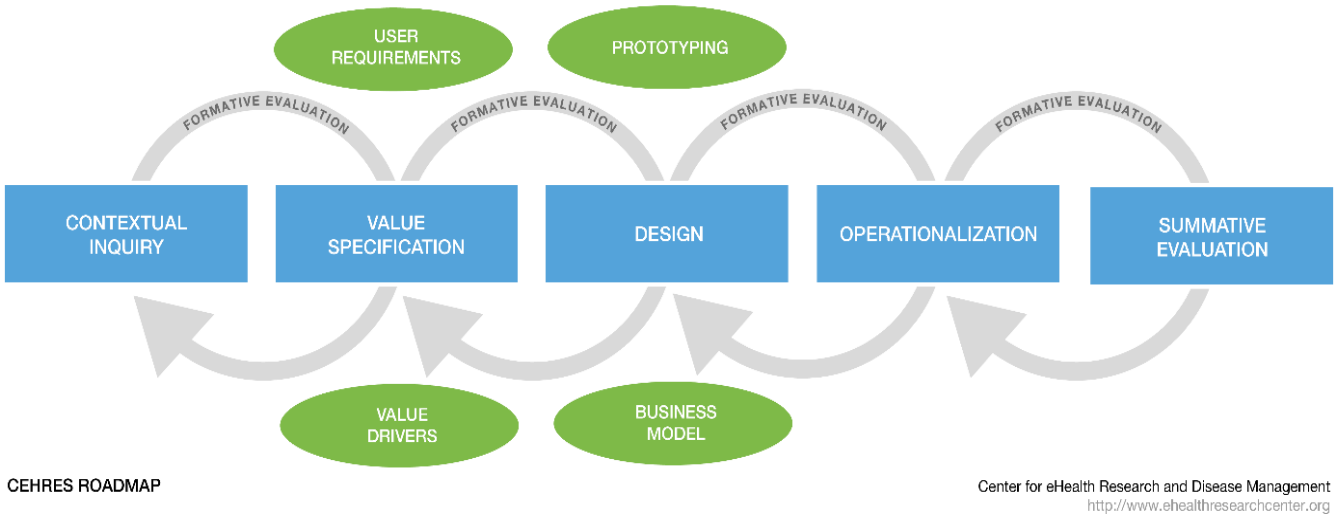

Figure 1. CeHRes Roadmap, adopted from van Gemert-Pijnen et al. (2011).

The CeHRes Roadmap clearly visualises how the process of developing and implementing a new technological tool is not a linear process, but rather a continuous process where adaptions can be made throughout the entire process. For the design step in the roadmap, the designers of Sense-IT utilised the Element-Method-Product (EMP) framework in order to develop the prototype (Derks, Klaassen, Westerhof, Bohlmeijer, & Noordzij, 2019).

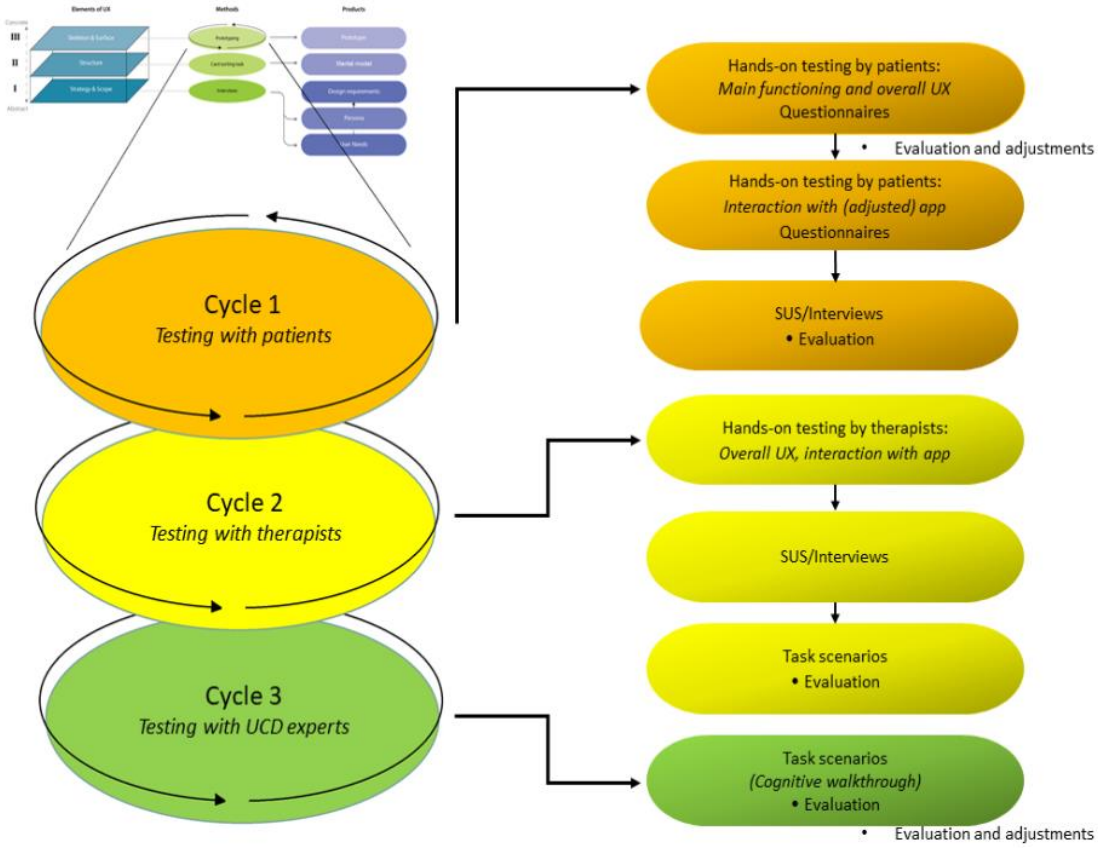

Figure 2. Element-Method-Product (EMP) framework, adopted from Derks, Klaassen, Westerhof, Bohlmeijer, and Noordzij (2019).

This consisted of iterative cycles where the client and therapist were included actively. This framework was also analysed for the purpose of the current research given the fact that it is a prototype based on UCD. The prototyping phase was conducted based on three iterative cycles, testing with patients, therapists and UCD experts as is visible in Figure 2. However, for developing a protocol for the adoption of Sense-IT, it could revised whether this order of cycles is appropriate. Later on in this section, this consideration will be made after the perspective of other theoretical frameworks and the user description was discussed.

Technology Acceptance

Implementing new eHealth technologies into mental health care was found to be challenging, however, these finding can be analysed thoroughly aiming to increase feasibility (Derks, Visser, Bohlmeijer, & Noordzij, 2017). In order to integrate Sense-IT, barriers, as defined earlier, were taken into account aiming to minimise their impact. This was done on two different levels: the adoption of electronic mental health in general and the adoption of Sense-IT in addiction treatment. The Level of Adoption eMental Health Model (LAHM) designed by Feijt, de Kort, Bongers, and IJsselsteijn (2018), explains five levels of adoptions, with the characteristics, barriers, drivers and requirements for change per level.

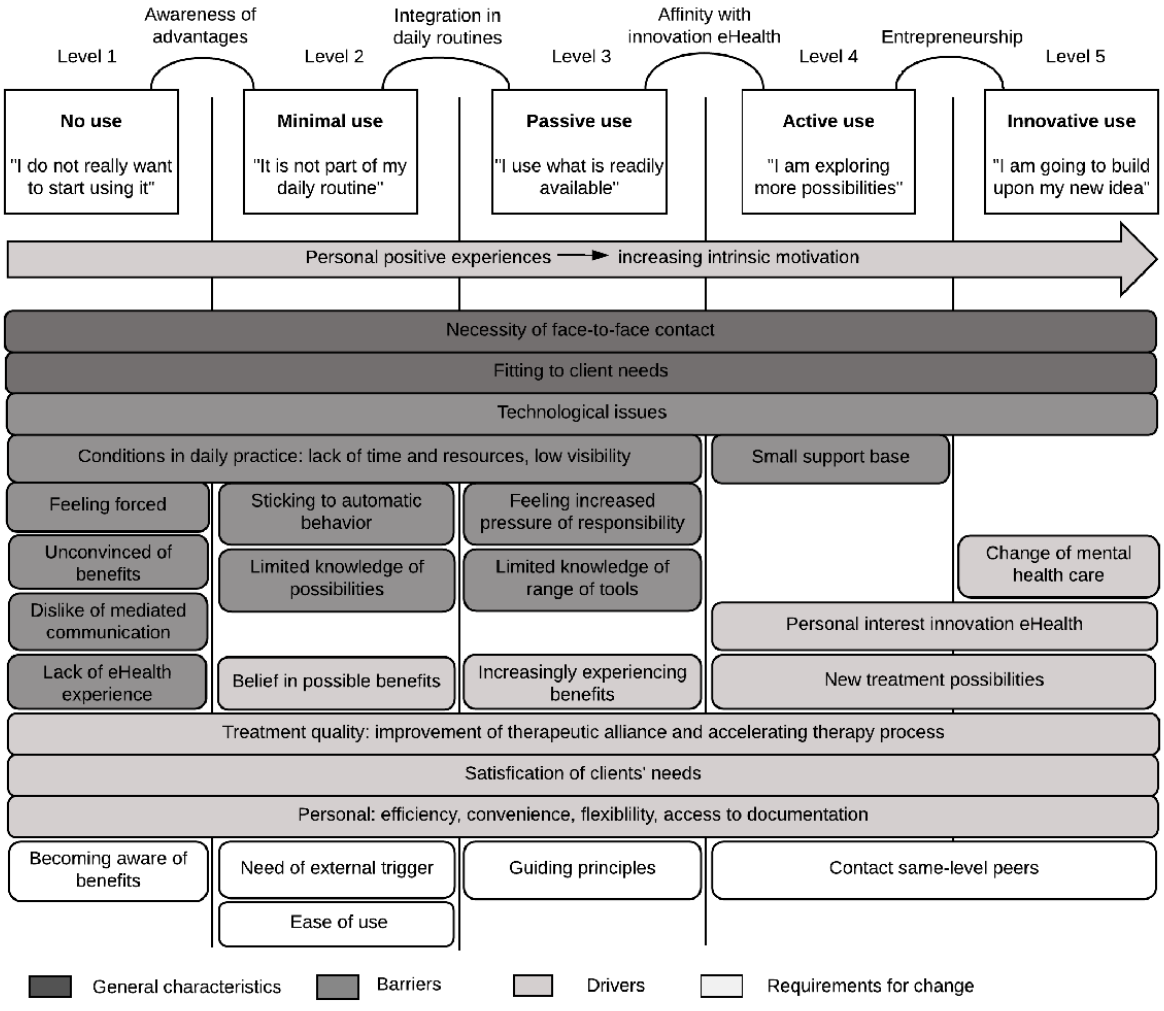

Figure 3. Level of Adoption eMental Health Model, adopted from Feijt, de Kort, Bongers, and IJsselsteijn (2018).

General aspects regardless of the level of adoption, such as fitting to the client needs and treatment quality can be anticipated upon by including the client and therapist into the designing process. This will enhance the personal positive experience of the adopter and therefore result in an increase in intrinsic motivation to use the Sense-IT protocol. The protocol is supposed to be an overview of all information that needs to be transmitted to the therapist for actual implementation of Sense-IT. This information needs to be tailored to the needs of the therapist in order for them to feel well-prepared, but also to elicit personal interest in the new treatment possibility by explaining the possible benefits and lower possible barriers, such as lack of experience. It was found that identifying personal drivers and barriers is of high importance for the adoption of new technologies in general (Buis, 2019; Feijt, de Kort, Bongers, & IJsselsteijn, 2018; Titzler, Saruhanjan, Berking, Riper, & Ebert, 2018).

As explained before, the extent to which biofeedback is effective in the clinical field depends on the user's perception, understanding and usage of the feedback. This can be enhanced by including the user in the design process of the protocol. One way to include the user into the designing process is to base the protocol design on the User Centred Design, which will be extended on in the following paragraph (Triberti & Riva, 2015).

User Centred Design for Technology Implementation

UCD as defined earlier, includes end-users in order to design a product aiming to reassure the requirements are met. The UCD, often referred to as Human Centred Design (HCD), approach consists of multiple phases as is depicted in Figure 4.

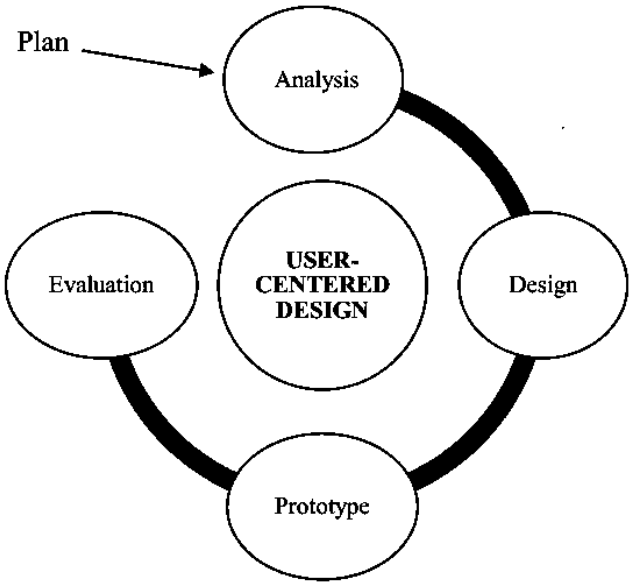

Figure 4. User- Centred Design model, adopted from (Shapi'i, Rahman, Baharuddin, & Yaakub, 2018).

During the plan phase, an overview is created including the goal of the company and will be taken into account for the product design. Analysis consists of a context analysis, user requirements and identifying the needs, goals and limitations of the users (Witteman et al., 2015). In the design phase, the design of the product can be made. The prototype phase implies development and testing of the prototype of the product. Then, this testing is followed by an evaluation, which also improves the final design of the product.

User Description

Within the UCD, a distinction can be made between different types of users. An identification can be made with the different types being: primary, secondary, tertiary users (Abras, Maloney-Krichmar, & Preece, 2004; Triberti & Riva, 2015). Primary users interact with the product directly. Secondary users are people who do benefit from the product or make use of it via an intermediary. Finally, the ones who are affected by the product and are responsible for the implementation or purchase of the product. Primary user of the protocol will be a professional, e.g. therapist, but the exact function needs to be determined. Secondary user will be the client. However, the primary user of the Sense-IT itself is the client, with the professional being the secondary user.

Given the fact that the main user of the protocol will be the therapist, it is convenient to commence with their experience and estimation of feasibility when it comes to the implementation of Sense-IT. Consequently, the protocol can be tested with clients and discussed for feedback. The Sense-IT prototype was checked by the UCD experts and was now ready for implementation. First, therapists and other professionals at Tactus could be interviewed in order to design the first version of the protocol based on semi-structured interviews, followed by testing that protocol with the clients.

The Current Research: Aims, Objectives & Research Questions

The present study aims to construct a framework using UCD in which the adoption of eHealth technology, Sense-IT, can be optimised in order to fit into the regular AUD treatment offered at Tactus. In sum, this framework will be a hands on protocol that therapists can utilise as an additional tool during the therapy sessions. This will be done in EMP framework as was opted for in the prototype design of Sense-IT itself. The first cycle includes the primary users, so therapists and other professionals employed at Tactus verslavingszorg, The Netherlands. Whereas the second cycle includes the secondary users, the clients. Furthermore, it was decided that there is no time available within this research to include the final UCD expert cycle of the EMP framework.

For this research the following objective has been constructed: design a protocol for the implementation of Sense-IT based on UCD within Tactus. Based on this objective, research questions have been formulated per cycle.

Cycle 1. Designing Protocol with Professionals

During this phase, the context of the user will be clarified and user requirements will be established. During the first cycle, the expected impact of the protocol for all stakeholders will be analysed. Then, a design will be created in order to meet those requirements. The primary and secondary users have yet been identified and are the professionals and clients.

The context of the user implies the identification of all intended users, the tasks, the environment, their goals and interests (De Vito Dabbs et al., 2009). It was decided together with the first supervisor and contact person within Tactus to pose more concrete questions where the requirements and context of the users were discussed thoroughly. The main reason for this decision was to make the protocol as concrete as possible. Evidently, for the protocol, it was necessary to know what exactly the professionals considered to be effective and feasible.

Aiming to construct a concrete protocol, the following research questions were formulated:

Specific Research Questions:

- What is the added value of Sense-IT in addition to regular clinical treatment?
- For which clients might the usage of Sense-IT be beneficial?
- What would a concrete session using Sense-IT look like?
- How many sessions with the Sense-IT are required?
- What is the preferred moment of using Sense-IT during the inpatient treatment?
- What is the optimal duration of usage in weeks/sessions? On which factors does this depend?
- How and what information should be transmitted to clients during the first instruction?
- How and what information should be transmitted to the professional in the protocol?

Cycle 2. Testing and Evaluating Protocol with Clients during Pilot

The second cycle commences at the point where a draft version of the protocol was created and the therapists support the outcomes. Within this phase, step four of UCD , evaluate the solution against the requirements, can be taken (Schulz, Fuglerud, Arfwedson, & Busch, 2014). This can be done by testing the protocol in a pilot with clients. By doing so, the

executive therapist and client are both able to evaluate on the extent to which their personal requirements are met.

Therefore, the pilot can result in strengths and point of improvement of the protocol itself. In addition, it is expected that practical recommendation can be formulated in order to improve the Sense-IT prototype. This phase will not require new research questions, but all answers of phase 1 can be revised. The overall research question of the current research will refer to the final version of the protocol.

Overall Research Question:

- In what way could biocueing with the Sense-IT application be used as part of regular inpatient alcohol addiction treatment?

Methods

Design

In order to answer the beforementioned research questions, a research design was developed as is presented in Figure 5. This research was divided into two cycles where one is focused on professionals and the other on the clients as in line with the UCD approach in the EMP framework as described earlier. In order to design the protocol for the implementation of Sense-IT in the inpatient alcohol addiction treatment, qualitative methods have been used in the different steps of the research. It was found that including stakeholders in the research is of high relevance for effective usage of the protocol (van Gemert-Pijnen et al., 2011). This research has been approved by the Ethical Committee of the University of Twente and by the scientific board of Tactus. The exact content of the two cycles was divided into three different steps and were presented in the process protocol design flowchart as presented in Figure 5.

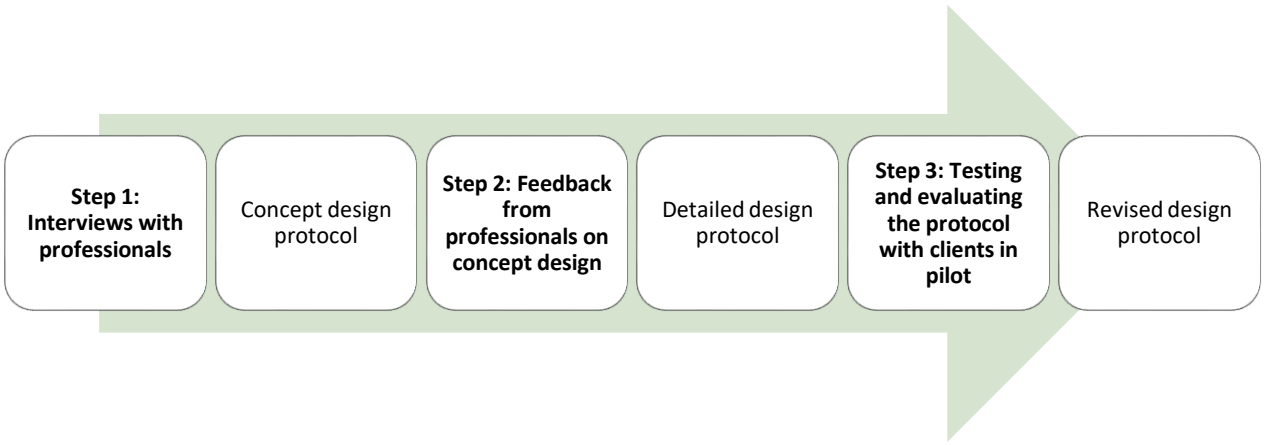

Figure 5. Process protocol design

Based on this process a full research design was designed including the methods and analysis. This can be found in Figure 6.

UCD cycle	**1. Data collection Professionals**		**2. Pilot with clients**
Step	1	2	3
Method	Semi- structured interviews via (video) calls.	Feedback in written comments, verbal discussion via (video) calls with supervisors and Tactus professional.	Face to face sessions guided by the detailed version of protocol with clients of the inpatient treatment at Tactus. Location: Raiffeisenstraat, Enschede.
Analysis	Transcribing and coding in Atlas.ti based on content analysis	Communicative validation.	Communicative validation & Conversation analysis.
Product	Concept version protocol	Detailed version protocol	Revised version protocol
Final result: protocol for the implementation of Sense-IT within the regular addiction treatment.			

Figure 6. Research design.

Justification Study Design

As stated before, this research is based on UCD in the EMP framework. In the following sections, an explanation will be given per step. This explanation will contain support for the motives that particular step is included and what it will contribute when it comes to answering the research question. In this research, both the needs of the user and the goal of the company, Tactus, will be analysed and taken into account for the protocol design. During the plan phase of the UCD, the goals and wishes of Tactus were included first in order to facilitate feasibility of the protocol.

Step 1: Interviews with Professionals. The first step enabled the clarification of the context of both primary and secondary users of the protocol. This was the analysis of the UCD model and included the identification of user requirements and needs (Schulz, Fuglerud, Arfwedson, & Busch, 2014). Semi-structured interviews with professionals provided them with the opportunity to share their perspectives, wishes and needs and at the same time share what their personal requirements were. The questions that were prepared answered the

specific research questions. Using semi-structured interviews for this purpose has been done more often with success, suggesting this seems a proper method for analysing the user's perspectives (Derks, Klaassen, Westerhof, Bohlmeijer, & Noordzij, 2019; Feijt, de Kort, Bongers, & IJsselsteijn, 2018; LaMonica et al., 2019). Furthermore, a language barrier was not expected, since the mother tongue of participants and researcher was Dutch, apart from one professional who had more than enough Dutch language skills. Another barrier that was not expected was social desirability, as this topic was not mainly sensitive for social desirable answers, making semi-structured interviews an appropriate method (Barriball & While, 1994) Also, this was an identification for the professional as well as for the client, since the professionals in general do have a clear perspective on their clients. This analysis was crucial in answering the specific research questions and design the first concept version of the protocol.

Step 2: Feedback Round with Professionals. This step was crucial in increasing validity of the protocol and obtaining more information in order to create the detailed version of the protocol. This was of high importance for the current study, since the adoption of protocol by the user can only be optimised when fully understanding the user. This is the iteration of the UCD cycle in which the concept design was analysed again and lead to developing a new design.

Step 3: Pilot with Clients. The final step was of high relevance and included for testing the prototype of the protocol and evaluating on it. This evaluation was done from the perspectives of the clients and of that of the therapist. By including both perspectives, it can analysed whether both parties see reasons to adopt the additional therapy with Sense-IT in such a format. Then the evaluation can be focused on the conceptual decisions, Sense-IT itself or focused on the concrete execution. By finishing testing and evaluating, the UCD cycle was completed and a clear perspective on the protocol design was obtained.

Design Guidelines

The semi- structured interviews were focused on creating the protocol. By doing so the context of the users became evident, but also other suggestions and barriers were put forward. These were for instance solutions for dealing with foreseen issues of which examples will be given in the result section. This is an important step in UCD (Jokela, 2002; Schulz, Fuglerud, Arfwedson, & Busch, 2014).

The protocol design itself was inspired by the existing protocol from Tactus and was written in Dutch. The format and layout were kept in the corporate design of Tactus as much

as possible in order to make adoption of the Sense-IT protocol as easy as possible for therapists.

For the prototype of the protocol a few usability principles were included namely: consistency, familiarity and simplicity (Mahemoff & Johnston, 1998; Nielsen, 2005). Evidently, a usability test was not conducted during this research and not all usability heuristics have been covered yet, but this was an important starting point for the visual on paper design of the protocol. The protocol was aimed to be consistent as a whole, implying that all aspects were discussed equally within the different sessions. Then, by using the Tactus corporate design, familiarity was intended to be achieved. Finally, the design was aimed to be simple, so that the adoption was as easy as possible. This was done by using simplified language, a clear font and a slightly larger line spacing. Also, necessary images were added exclusively. Furthermore, important technological settings were simplified in flowcharts, which were included in the protocol. It was found that the protocol is often adapted by the therapist as well as by the client, meaning that a rather simple protocol is less sensitive for interpretation errors (van Dooren, Visch, Spijkerman, Goossens, & Hendriks, 2020).

Participants

Participants were professionals (n=5) and clients (n=2) recruited from the inpatient treatment department of Tactus Addiction Treatment in Enschede. The multidisciplinary group of professionals, including therapists, was selected based on convenience sampling analysing suitability and availability. Clients were recruited based on the same principles, which were estimated by the professionals and depended on the client their own willingness to participate. It was aimed to include only clients with a primary alcohol problem, however, that was not feasible due to the small number of AUD clients in the clinic. Therefore, clients suffering from other addiction disorders were approached as well. The description of the participants was of high relevance to put in perspective what was said. Therefore, the participants were divided into two categories: professionals and clients. In those paragraphs a thorough description of the participants was presented. In order to maintain the privacy of the participants some personal information was left out.

Professionals

In Table 1, the demographics per professional (n=5) are presented.

Table 1

Profile professionals

Professional	Function	Location	Age	Gender	Nationality
1	Medical director/psychiatrist (MD/PhD)	-	64	Male	Dutch
2	Nurse Practitioner MSc	Rekken	56	Female	Dutch
3	Healthcare psychologist	Enschede	37	Male	Dutch
4	Researcher	Rekken	26	Male	German
5	Healthcare psychologist in training for clinical neuropsychologist	Enschede	41	Male	Dutch

Clients

Only two clients finished the entire pilot. Both clients were men, Dutch and aged 42 and 43. Client 1 had a primary alcohol addiction and has been in and out of clinical and ambulatory treatment since 2011. The main trigger was beer consisting of 10% alcohol in .5 litre cans. At the start of the pilot, this client was in the fifth week of the inpatient treatment. His main objective to drink was to eliminate rumination mostly during the evening at home on the couch. Client 1 had not worked ever since his addiction started. Before that he used to be a draftsman and civil engineer. Client 2 had a primary cocaine addiction for three years and had been in ambulatory treatment once before. At the start of the pilot, this client was in the fourth week of the inpatient treatment. He used cocaine out of routine and especially after a stressful situation where several emotions were experienced in order to forget and release tension. For example, this client could not handle perceived misplaced criticism, implying that this was

often a moment where he would visit his dealer. Client 2 ran his own business together with this father.

Both clients mentioned before the pilot started already that they were not able to recognise cravings and did not really experience those in the clinic.

Covid-19

During this research the global COVID-19 pandemic was reason for an intelligent lockdown in the Netherlands. Therefore, the research was not completely conducted as intended. The interviews with the professionals were supposed to be face to face interviews. However, these were interchanged with online (video) calls. This also implies that the professionals had not seen or tried the Sense-IT during the meeting, which made it more difficult for them to give input for a protocol with the Sense-IT.

Furthermore, during the interviews with the professionals, it was uncertain which form the pilot with clients would have. Therefore, not all interviews were conducted from the same perspective. For instance, the introduction session was discussed in the form of a video, a flyer or a real-life session.

Then, it was intended to tailor this research to ambulant treatments given the fact that Sense-IT is particularly suitable for bio cueing. However, the ambulant treatments were not offered on a regular basis due to COVID-19, so this was part of the reason it was decided to offer Sense-IT to an inpatient treatment population. However, this could also be a proper preparation for when the client leaves the clinic and starts ambulant treatment.

The original plan for the cue exposure was to offer cues by means of Virtual Reality. Unfortunately, all research using VR was paused due to hygienic and safety reasons. One of the interviews with the professionals was completely tailored to that, making that interview less useful for now. Alternatively, it was decided to offer cues digitally and realistic instead.

All materials were disinfected as was prescribed and distance was kept at all times.

Materials / Technology

Sense-IT

Sense-IT was used on both smartwatch and smartphone and functions as a biosensor by measuring heart rate.

a *b*

Figure 7. Smartphone application (a) and smartwatch (b) layout by Derks, Visser, Bohlmeijer, and Noordzij (2017).

As is presented in Figure 7, the physiological data collected by the PPG sensor in the wearable, will be depicted in circles on the smartwatch as well as the smartphone. The frequency of measuring can be altered in the function 'settings'. These points of measurement will be translated into a scale of minus three to five and will be depicted with circles on both the smartwatch and -phone with the larger, fourth circle being the personal baseline. These circles share information with the user concerning the heart rate, so when more than four circles are depicted, the heart rate is higher than during the baseline and when less circles are depicted, the heart rate is lower compared to the baseline. When a higher high rate is measured, the smartwatch will provide the user with haptic and visual feedback in the form of vibrations and an exclamation mark on the screen. The user is able to adjust the circle on which the feedback will be offered. For each individual measurement, the user can indicate the level of arousal on a scale from 0 to 10 on the smartphone and can also add the context of measurement by means of a small diary. This is important since the heart rate sensor does not distinguish between physical or mental arousal. Desirable is that if the heart rate is analysed for a while, the user has obtained more individualised information on the physiological processes that are experienced together with psychological factors or the ones who are not. The goal of Sense-IT is to make the user more aware of the heart rate that is registered when

cravings are experienced. As explained earlier, higher heart rate can be an indicator for cravings, but this is obviously not the case for each individual (van Lier et al., 2017).

Procedure

In the design section, all steps per cycle were described. In the following paragraphs the content and procedure of those steps will be explained more extensively.

Cycle 1. Designing Protocol with Professionals

Step 1: Interviews Professionals. During the individual semi-structured interviews, input was retrieved from the professionals by means of asking open ended questions in order to create the first version of the protocol. All interviews were (audio) recorded for verbatim analysis. The main objective of the interviews were to identify the user's needs and requirements for the content of the protocol. The interviews took place in the months of April and May 2020. Each professional was asked what their perspective was on certain topics. These topics were: the added value of Sense-IT, for which clients the Sense-IT would be suitable, what a concrete session with Sense-IT would look like, the amount of sessions needed, the preferred moment in the regular inpatient treatment, the optimal duration of each individual sessions and which information should be transmitted to the clients and which to the professional. All other relevant, additional remarks were included as well. In addition, basic background knowledge into Tactus, the research and Sense-IT were included as well and created a perspective on the user's context. The perceived way of working at Tactus differed per professional and were discussed thoroughly as well. The goals and ideals of Tactus were considered just as the feasibility and perceived room for innovation. Ideas and suggestions from the first interviews were discussed in the interviews scheduled later on in order to verify them, which is effective when striving for information saturation.

Step 2: Feedback Round. After the five interviews were performed, the concept version protocol was developed and proposed to the professionals involved for their feedback. Discussion points and dissensions were solved in a meeting with the first supervisor and professional from Tactus. Adjustments were made in order to construct a feasible protocol. Then, both supervisors provided another round of feedback on the protocol. These included both a proper perspective on the way of working at Tactus and the in-depth explanation of Sense-IT. Including all this feedback lead to the detailed version of protocol and was utilised in the pilot with the clients.

Cycle 2. Testing and Evaluating with Clients during Pilot

Step 3: Pilot with clients

Introduction Session. A meeting needed to be planned in order to inform all stakeholders on the utilisation, practicalities and user advantages of Sense-IT. The content of this meeting is determined by the interviews with the professionals, a literature review and current used protocols (‘handleidingen’/ ‘draaiboeken’) within Tactus. During this introduction session, the clients received an explanation on the process of the research. This included the schedule with which moments they were asked to attend. In addition, the Sense-IT was thoroughly explained. A baseline was set together with the researcher according to Figure 8. This flowchart is based on a working document created by ter Hamsel (2020) from Inforsa where a protocol is being designed for Sense-IT within aggression regulation training. Finally, cue identification was conducted in order to provide the best cues possible for each client individually.

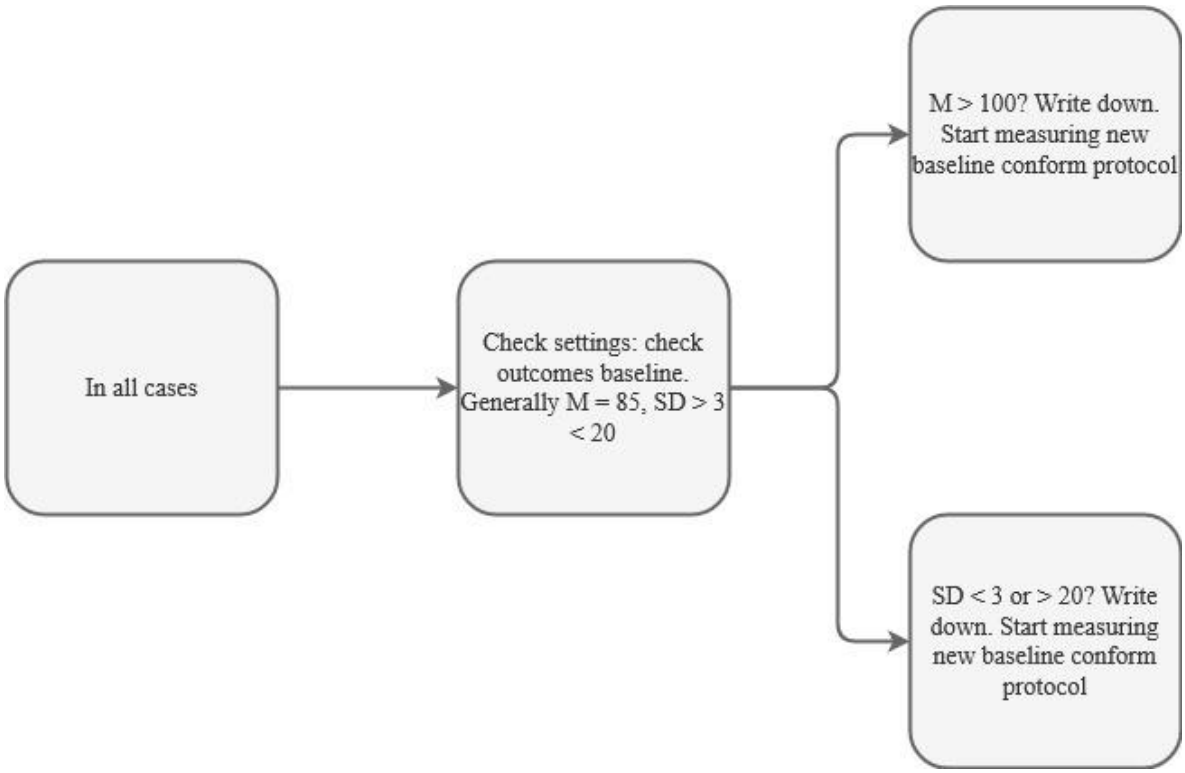

Figure 8. Baseline procedure Sense-IT

Sessions with Clients. During the sessions, the client was asked to undergo cue exposure in order to elicit cravings and analyse what happens mentally as well as physically. They were asked to describe what they felt and what that means for them. Moreover, clients

were asked to evaluate on the Sense-IT app used in treatment and added value for themselves, if applicable. Conceptual factors that were established in earlier steps of this research, e.g. the duration of the pilot, duration of individual sessions, the activities within one session and the moment in their treatment, were evaluated. Opinions were noted during the sessions and all points of feedback were considered together with the supervising healthcare psychologist for a third version of the protocol. During the sessions, the baseline could have been measured again in order to conduct the sessions with a smaller mean and standard deviation. However, this was not necessary for the clients, given the fact that their heart rate and standard deviation were already rather low. It was discussed whether they would want to adapt the baseline for the time outside the sessions in order to prevent continuous vibration, which was not found to be necessary by both the clients.

Analysis

Step 1: Interviews with Professionals

First of all, all recordings of the interviews were transcribed and analysed using the software package ATLAS.ti. The qualitative analysis was conducted based on content and themes. The analysis was conducted based on qualitative deductive content analysis, which implies that information was filtered based on criteria that were determined prior to the data collection (Flick, von Kardoff, Steinke, & Jenner, 2004). More specifically, these criteria were constructs that were compatible with the beforementioned specific research questions. Content analysis seemed a suitable method and its limitations were taken into account. One of the limitations as described by Flick, von Kardoff, Steinke, and Jenner (2004) is that this method is not optimal for research questions that are rather open. This was not the case in this study, given the fact that multiple specific research questions were analysed in this step. Furthermore, studies with an inductive and remarkable exploratory character rather utilise different methods. This all is not linked to this research, making deductive content analysis an appropriate option. The trustworthiness of content analysis depends on multiple factors. The preparation prior to the interview is of high relevance for the trustworthiness (Elo et al., 2014). Trustworthiness here can include for instance, credibility, validity and transferability. Given the high relevance of preparation, all interviews were thoroughly prepared and particular questions were formulated per professional adapting to their specific field of knowledge. For example, the professional with most knowledge on Virtual Reality was asked what options were available with regards to offering cue exposure using VR. Moreover, content analysis reassures inter-code reliability since it measures against itself (Flick, von Kardoff, Steinke, & Jenner, 2004). The themes were analysed based on verbatim thematic

analysis in which the patterns of themes are identified, analysed and interpreted (Braun & Clarke, 2006). Themes are the pieces of information that contribute to answering the specific research questions. It was necessary for the protocol to search for patterns within the answers to the specific research questions. Thematic analysis is widely used in the context of Psychology and one of its strength is the flexibility of analysis that it provides (Braun & Clarke, 2006). In this research, the eight themes that were identified were: (1) Added value of Sense-IT, (2) For which clients, (3) Concrete session with Sense-IT, (4) Amount of sessions, (5) Preferred moment in treatment, (6) Optimal duration of sessions, (7) Information transmission to clients, (8) Information transmission to professional. Quotes by both professionals and clients will be utilised to illustrate statements.

Step 2: Feedback Round

Data retrieved from the feedback round with the professionals (step 2 from the research process) was analysed using communicative validation, which is an interpretive approach which is utilised in order to establish truth (Sandberg, 2005). Communicative validation is often used in order to justify empirical findings and aims for coherent interpretations. It is also utilised for testing subjective interpretations for validity (Kvale, 2007). The main objective here was to come to a collective judgement on all specific research questions and to validate the opinion of one another. Also, the appropriateness of the decisions that were included in the protocol were discussed on a conceptual level. The feedback was provided by means of comments attached to the protocol. Only with consent of all professionals, the concept version was adapted and a detailed version was created using the feedback of the professionals. All feedback was discussed with both supervisors and the professional responsible for research at Tactus via a video call. This was analysed and dialogical intersubjectivity was aimed for (Kvale, 2007). The latter implies that during the video call by means of discourse, agreements were made and noted. At the end of the meeting, these agreements were listed in order to be as clear as possible about the subjective interpretation of the agreements and to facilitate validity by means of communicative validity.

Step 3: Pilot with Clients

During the pilot, the data was retrieved from verbal quotes from the clients. Relevant remarks and findings were written down verbatim and were analysed together with the supervising healthcare psychologist. This way of establishing validity is known to be an effective approach in the variety of approaches (Sandberg, 2005) In order to increase validity, communicative validation was used during the sessions. As explained before, this implies that during the sessions, the researcher asked for clarification on those relevant remarks to ensure

proper understanding. However, communicative validation is not sufficient when it comes to the coherence between people their behaviour and promises or remarks (Sandberg, 2005). In order to cover that part, pragmatic validation was implemented. Pragmatic validation is related to testing the action based knowledge (Kvale, 2007; Sandberg, 2005). This was done during this study by means of asking for concrete examples and by means of the guided fantasy in which all compartments, e.g. smell, emotions, environment, thoughts and actions, were included. As stated before, these types of analysis all took place during the data collection. However, this simplified the analysis after the sessions with the supervising psychologist.

Results

Results obtained in each step of the designing cycles will be presented. First, this section will present the outcomes of the interviews with the professionals, step 1, in which all specific research questions were answered by all professionals. Secondly, all feedback from the professionals and both supervisors, step 2, retrieved by written feedback and oral discussion are included. An overview is created of all main decisions that were made and incorporated in the detailed version of the protocol that was used during the pilot, step 3. Then, the feedback retrieved during the pilot will be discussed in the perspective of the client and in that of the researcher and supervising therapist. Finally, a new overview will be depicted in which all feedback was adopted for the final, revised version of the protocol.

Step 1: Interviews with Professionals

Analysis of the five interviews with the professionals resulted in eight main themes each answering one specific research question. Those have been established based on an deductive content and thematic analysis and are labelled as: Added value of Sense-IT, For which clients, Concrete session with Sense-IT, Amount of sessions, Preferred moment in treatment, Optimal duration of sessions, Information transmission to clients, Information transmission to professional. Based on the five interviews, no other themes were identified.

Added Value of Sense-IT

Definition: What is the added value of using Sense-IT in addition to regular inpatient treatment of alcohol addiction.

Codes: Advantages, Examples, Emotional aspects, Skills, Innovation

These results offered an insight into possible drivers several different adopters may experience when opting for Sense-IT. This is relevant for technology acceptance as was argued earlier. By clarifying the drivers of this small sample group, their ideas can be used to attract more interest from other employees of mental health care when this is described in the protocol.

All participants were able to produce a theory on how Sense-IT in fact could have added value in addition to the regular treatment. Two of the professionals argued that the added value is the increased awareness the clients may experience because of the biofeedback.

- *"The added value I suppose is the fact that the focus can be easily put on craving and physical experiences and connect those to craving. Often, this is considered to be difficult." (P2) –*

Another advantage that was included by one of the professionals is working with cue exposure to experience cravings in a controlled setting. Nothing has been done to induce or train with cravings during the inpatient treatment so far unless it spontaneously appears, therefore, Sense-IT would be an innovation by including cravings in the treatment. It was mentioned that this may include the training aspect of anti-craving techniques, so it includes the connection of physiological reactions accompanied with craving and it may be a catalyst for conversation with the therapists.

In addition, an example of the added value of Sense-IT in specific was mentioned compared to previous research with the Empatica E4 wearable by (van Lier et al., 2017). Sense-IT is able to classify movement, such as running, walking and driving a car, which explains an increased heart rate. Furthermore, Sense-IT is easy to utilise for all clients, so it holds a lower threshold for utilisation and is more cost efficient.

- "*Another advantage of Sense-IT is that it can distinguish if the user is running, walking, cycling or driving a car. So, Sense-IT is simple and has a lower threshold to utilise." (P4)* –

In sum, the added value of Sense-IT in addition to regular inpatient treatment is an increase in awareness, the training with cravings, to function as a catalyst for conversation, the intelligence of Sense-IT by detecting movement and the easiness to utilise Sense-IT for the majority of the clients.

For which Clients

Definition: For whom is the addition of Sense-IT to regular inpatient treatment of primary alcohol addiction most beneficial.

Codes: Inclusion criteria, Exclusion criteria, Characteristics, Approaching clients.

In this theme, the client target group was specified together with the professionals. A clear client persona needed to be created to obtain general understanding of the clients of the inpatient treatment at Tactus. This was important since the content of the protocol needed to be tailored to this group. Therefore, a proper understanding of their requirements, needs and situation was of high relevance.

Generally, all professionals were positive that the majority of the clients in inpatient treatment would be suitable for this research. This would offer a wide group of clients the opportunity to use Sense-IT, but also implies that the persona of the clients for the protocol might be less specific.

For research purposes the clients need to be interested in this research according to two of the professionals. In addition, only clients who have finished the detoxification can be

included, since the physical withdrawal symptoms during this period can alter the physiological responses.

An exclusion criterion that was suggested is a limitation in intellectual capacity. One professional argued that clients need to understand the wearable, smartwatch and app and should be able to work with it individually.

- "*Actually, I think that only people who lack the intellectual capacities are not able to work with a thing like this. Uhm.. but other than that, I think that it will work for everyone if I think of the client population." (P3) –*

Moreover, it should be examined per client, suffering from e.g. a neurological disorder, epilepsy, the usage of particular medication or cardiovascular diseases, if this intervention is beneficial for them. For instance, the usage of medication could alter the blood pressure or heart rate prior to the cue exposure, making the biofeedback less representable.

- *"Exclusion criteria seem to me people with a neurological dysfunction. For instance, people who suffered from CVA in the past." (P5) –*

Another comment that was made by a professional is asking the clients if they would be able to handle cravings in case they appear. In case of a negative response, it is important to explain the importance of training those feelings. However, an experienced professional is advised to make an estimation whether the timing is right for that client.

In sum, the majority of the clients who have finished their detoxification would be suitable for this research. Interest in the topic, using technological devices in addition to the regular treatment, would be helpful. In case of reduced intellectual capacity or physical challenges, professionals should examine per patient whether this intervention might be beneficial.

Concrete Session with Sense-IT

Definition: What a session with Sense-IT would look like and which elements it needs to contain for clients with primary alcohol addiction.

Codes: Schedule, Activities, Cues, Practicalities during execution, Explanation during session

For this theme, the specific needs of both the professionals as well as those of the client were analysed. This will include the entire content of the sessions with Sense-IT. It needed to be decided how exactly Sense-IT could be utilised so that optimal advantages could be experienced. Also, the professionals are the only ones who know what the exact content is of the existing program and how the training with Sense-IT could add to that. Furthermore, the order of those activities needed to be established so that the client would not experience any craving right before leaving the room. Then, practicalities during the session were of high

importance to map out. Here, some barriers were detected, which solutions needed to be searched for.

All professionals were convinced it is best to offer the sessions with the Sense-IT on an individual basis to prevent distractions from others compared to group therapy sessions as is common in the current treatment program, 'Verslaving de Baas'.

- *"Yes, I think in our clinic, you should separate that from the 'Verslaving the Baas' sessions in a group. Then you should plan another session with some clients to offer the sessions then." (P3) –*

On the other hand, the designated person to offer those sessions was a point of discussion for this research as well as for the long-term perspective for Tactus. All employees from the clinic in Enschede are already busy and do not have time to offer individual sessions. Therefore, as a solution to that issue, it was suggested by one of the professionals to offer the session in group environment anyway based on the feasibility on the long term. On the other hand, group sessions with more distraction may lead to less focus on the cues, which may result in less intense cravings. This would not provide clients with the optimal chance to train with these feelings. However, for this research, the researcher will be providing the sessions under supervision of the coordinating healthcare psychologist of the department from Tactus as was suggested by three professionals.

When it comes to the exact content of the sessions all professionals agreed on starting with an introduction for that session where the purpose is explained followed by the training with cues. Afterwards the experiences of the client can be discussed extensively.

- *"So, I would say something like an informative start, then the cue exposure and then a discussion." (P2) –*

The cues were suggested to consist of three alcohol-related cues and 2 discriminatory cues that result in arousal other than that evoked by substances. The suggestions concerning the cues, were all agreed upon by the other professionals. The discriminatory cues would have the function of establishing familiarity with arousal and increased heart rate. By including these cues, it is hoped that the client is able to distinguish arousal elicited by cravings or by other factors. This is valuable for recognising cravings sooner. The possibilities of offering those cues with Virtual Reality (VR) were researched. VR would offer some benefits in offering cues, due to the fact that the experience is more realistic and it facilitates embodiment. However, due to the beforementioned global COVID-19 pandemic, realistic cues or cues presented in a video are feasible for this specific research. The first alcohol-related cue is decided to be a focus on the alcohol itself, a video was suggested where the

most popular drinks, beer and wine, are visualised in an attractive way. The second cue can be focused on the location of common alcohol consumption, e.g. a bar or café. Finally, the accompanying emotions can be included in the third cue when emphasising the social aspect of drinking, including loneliness, depression or abandonment. The discriminatory cues will be one that builds tension during the video and the other one will be a jump scare.

- *"So that one is focused on the drink itself, one on the environment and one, let's say, on the emotional side. And you could consider the social aspect of it, of being accompanied." (P1) –*

In sum, individual sessions consisting of an introduction, training with cues and discussion was agreed upon. For now, sessions will be provided by the researcher supervised by the coordinating psychologist. The cues consist of three alcohol-related cues and two discriminatory cues that result in arousal.

The Amount of Sessions

Definition: How many sessions with Sense-IT would be optimal for clients with primary alcohol addiction.

Codes: Exact number, Period in between sessions.

After defining what the individual sessions should contain, it was important to estimate how many sessions would be beneficial for the clients. Here, the same barrier was perceived that professionals have limited time recourses. This might influence the amount of sessions that are possible. On the other hand, effectivity of those sessions and offering the mental health care the client needs is also of high significance.

When it comes to the amount of sessions, three of the professionals agreed upon two sessions with the Sense-IT in addition to the regular treatment. They argued that that should be sufficient when the objective is to increase (bodily) awareness and function as a catalyst for conversation. The other two professionals claimed three sessions to be more effective.

- *"In order to make them a topic for conversation and that the patients have an idea of what it does, yes 2 would be enough." (P5) –*

Two of the professionals would offer the sessions on a weekly basis, since all programs are scheduled in weeks. Another professional argued that only one or two days in between the sessions would be sufficient to test the second session on arousal caused by the new therapy form rather than the actual cues.

- *"From a scientific point of view, I would say two sessions would be pleasurable. To see how consistent the patients respond to the cues. That you offer the same cues with a few days, 1 or 2, in between to check if the response*

is not solely based on nerves from the unknown. If he has had the cues once, maybe he has a different perspective towards those cues or experience them differently." (P1) –

Since not all professionals were in the right position to answer this question, this discrepancy was discussed more thoroughly during the feedback round. To conclude, two or three sessions with a few days or one week between the sessions was examined further during the feedback round.

Preferred Moment in Treatment

Definition: Where in the regular inpatient treatment are the sessions with Sense-IT preferred for optimal impact for clients with primary alcohol addiction.

Codes: Individual recovery, 'Verslaving de Baas' program.

Now that it is conceptualised what the sessions should contain and how many sessions that requires, it was needed to orientate when it comes to the timing of the implementation of Sense-IT sessions. Beforehand, it was clarified that this is a first step in using the Sense-IT in the field of addiction treatment. Sense-IT is an ambulatory biofeedback app, which is originally designed for daily usage outside a clinic. However, it was reckoned to be crucial to start in a clinical setting in order to test the Sense-IT first. The idea is that clients can practise using Sense-IT in this controlled setting and learn how to utilise Sense-IT correctly. Then, it can eventually be taken into the ambulatory treatments. This pragmatic decision resulted in the fact that this question was already rather specific. Therefore, professionals were asked where in the eight weeks of inpatient treatment Sense-IT would be optimal to implement.

All professionals shared the opinion that the sessions with the Sense-IT are best scheduled after the period of detoxification. The (physical) withdrawal symptoms can alter the physiological response of the body making biofeedback less representative. This is a period of four to eight days and the clients are not in the same clinic as during 'Verslaving de Baas'.

- *"I would start immediately when it is possible. I think that the detox phase is not suitable, but generally they will be clean when they arrive and usually they commence 'Verslaving de Baas' the week after. They stay for a period of 8 weeks, so I would not know why this should start later, so I reckon week 2 or 3." (P3)* –

The professionals were interested in combining these sessions with the anti-craving techniques tackled in some of the sessions in the regular program. However, those sessions are solely focused on cognitive techniques and are not set for an individual recovery plan. The regular sessions of the 'Verslaving de Baas' program are continuous whereas clients can join

anywhere in the program until they have participated in all sessions. Therefore, linking the Sense-IT sessions to a specific session in the regular treatment will be timed differently for each individual.

In sum, the session with Sense-IT will be scheduled after the period of detoxification. The exact moment was be a point of discussion during the feedback round.

Optimal Duration of Session

Definition: How long should one session with Sense-IT take for clients with primary alcohol addiction.

Codes: Duration in minutes.

The content of the sessions was necessary in order to estimate the time required to execute all activities. The experience of the professionals was rather similar. All professionals shared the vision that one session should approximately take around 45 minutes. The fundament of this decision is the attention span of the client.

- *"The 45 minutes is a good one to stick to. That is something we actually always do. The attention span can no longer be maintained." (P2)*

Within Tactus all sessions take 45 minutes, which seems to be the optimal duration for clients to focus. This is tested before and has indicated that 45 minutes is desirable. To conclude, the sessions with Sense-IT will take approximately 45 minutes.

Information Transmission to Clients

Definition: What information should be shared with the client prior to the first session with Sense-IT.

Codes: Process related, Research related, Objective, Attitude

The focus of this theme is the communication towards the clients. After the protocol is finished, it is desirable that clients are interested in the new sessions and that they volunteer to participate based on the information that they will be given. In order to optimally attract clients, it is important to brainstorm on the content and form of that information transmission. Professionals know their clients best and have experience again with the communication with their clients. This theme explores the option in formulation, relevant information and ways to make the sessions with Sense-IT most appealing. However, the form of the information transmission to the client was ambiguous due to the global COVID-19 pandemic. Therefore, this was not discussed equally with all professionals. On the other hand, create ideas were mentioned that might now have been even thought of without COVID-19.

The information transmission could be presented in the form of a video, flyer or in real life depending on the current COVID-19 situation. All professionals considered a video to be

a great alternative for an in real life explanation. This video can be shown to clients on the iPad available in the clinic. A flyer would work as well unless too much information is presented on it. On the other hand, a video would make the sessions and this research more personal, which might result in more enthusiastic clients. Therefore, in case the real life briefing was not realistic, it was opted to create an informative video.

The attitude towards the information transmission should be focused on the positive aspects of the research, e.g. the added value, and it was advised by all professionals to keep the instructions as simple and short as possible, avoiding jargon or difficult words. It was shared that the client generally does not feel too good about him- or herself and that they usually like to participate in order to return a favour. Advised was to explain that they will help future clients by participating in this research.

- *"People suffering from addiction in a clinical setting, but also in other places, often feel bad about themselves. They think: 'Yes, I have done something wrong', 'I am a loser', all those negative thoughts. Often, they reckon it to be very nice if they have the feeling they can do something in return. So, what we really stressed was that "You are helping other addicts in the future." They felt very comfortable with this approach was told later on quite often." (P2) –*

When it comes to the content of the information, it was recommended to elaborate on why this research is interesting for them to participate, what is going to be done, what the objective is and explain that this is an innovation for alcohol addiction treatment. So, covering these topics with a positive attitude would be most desirable.

- *"Offer a proper explanation and that it has the objective to make mental health case more suitable and improve it. It is an innovation for mental health care, so I think, if you are able to put that into words, simple, not too long, no difficult words, with some energy, then I think you have done a good job." (P5) –*

To conclude, the mean to transfer information to the client is initially a real life briefing with the option to show a video. This briefing should contain information concerning the objective, the procedure, what is in there for them and why this research will be conducted. This should be in a simple, positive manner without jargon.

Information Transmission to Professional

Definition: What information should be shared with the executive professional prior to the first session with Sense-IT.

Codes: Protocol content, Technological skills.

Then finally, all this information must be formulated properly in the protocol. The professionals are the user of this design and the objective is to ensure that they feel motivated to use it. When looking at technology acceptance, all categories of adopters ideally feel capable and motivated to use Sense-IT and its protocol. Therefore, proper (written) communication with the professional by means of the protocol was examined with this theme. This included the content of the protocol as well as the technological support for the app.

The professionals all suggested to include a rationale clarifying the objective of the research in the protocol, as well as basic information on Sense-IT, the process including the steps that will be conducted and what the added value is. It was explained that clear instruction should be written in the protocol including what to do exactly, in which frequency and for how long. In addition, one professional proposed to add a contact person with phone number in case the executive practitioner is unsure what to do. These exact descriptions are required for the executive professional in order to make them feel comfortable with the therapy sessions they will have to give.

- *"I think an instruction of what they should do exactly. Often people find it helpful to know so that they will feel well prepared for their job. So, I would make sure that you have a proper protocol of what to do, how often, for how long and what to do or who to call if you are lost. To make sure that is well explained." (P2) –*

Moreover, all professionals claimed the employees of Tactus to possess sufficient technological skills to work with Sense-IT. However, they would include a manual for all technological settings in either the form of a written manual or an instruction video to explain Sense-IT in specific.

In sum, including all available information in the protocol is requested. The employees of Tactus have the technological skills required to conduct the sessions with Sense-IT, but a supporting manual would make professionals feel more comfortable when executing the sessions.

Step 2: Feedback round concept protocol

The information obtained in the five interviews with the professionals was utilised in order to create the first version of the protocol. This concept version was rather short and no examples were included in this version yet. Questions that arose while designing the first

version, were included for professionals to answer. The most important aspect of this version was to check the content of the information and check whether the professionals agreed with one another on a conceptual level and to verify whether everything was understood correctly.

The concept version was sent to all professionals by email in order for them to provide feedback. All written remarks were altered or included in the protocol. Remarks included suggestions on more detailed explanations, example questions and formulations for instance. Formulations were adapted, constructs were explained more extensively and example questions were designed. Professionals found example questions to be of additional value for making the therapist feel more comfortable while giving the sessions. On a conceptual level some ambiguities as defined earlier, were resolved. It was agreed upon the idea of offering two weekly sessions with the Sense-IT. However, an introductory session was offered three days before the first session, so the client has the opportunity to get used to the Sense-IT. In addition, the clients were asked to hand in the Sense-IT set in between those two sessions and no homework was given. The few ambiguous topics that appeared during this feedback round were discussed over a video call with the first supervisor and the medical director/psychiatrist of Tactus. During this meeting it was recommended to link the sessions with the Sense-IT to session eight from the regular 'Verslaving de Baas' program. However, after a discussion with healthcare psychologist of the clinic, this was not feasible for this research given the weekly inpatient schedule and small client population due to COVID-19. This is a clear example of barriers that are experienced and the difference between optimal and feasibility as became evident during this research. The optimal scientific background and feasibility in practice are found to be not always equal.

Finally, it was decided to offer the cues in a different format. Small videos would not be sufficient to induce cravings. Therefore, it was suggested to offer cues by means of a guided fantasy in order to elicit cravings. This guided fantasy included the same aspects as discussed earlier, the drink, the environment and social/ emotional aspects and tailored questions to the overall senses. In addition, it was decided to keep the discriminating cues in the form of videos. The order in which these cues were presented was random with the purpose to minimise measurement errors. In Table 2 the main decisions are listed per specific research question and were directly included in the detailed version of the protocol.

Table 2

Overview conclusion per theme after feedback round

Theme	Conclusion
Added value of Sense-IT	Increases awareness on physiological processes during craving and stress/arousal.
For which clients	All clients after the detox phase without reduced intellectual capacity.
Concrete session with Sense-IT	15 minutes explaining and discussing Sense-IT and experiences with regards to cravings. 15 minutes training with cues, including guided fantasy, and anti-craving techniques. 15 minutes discussing and reflecting on findings.
Amount of sessions	One introduction session, two sessions with Sense-IT.
Preferred moment in treatment	After detox phase, connected to 'Verslaving de Baas' session 8.
Optimal duration of sessions	45 minutes per session.
Information transmission to clients	Basic information on what it is that will be done and why. Basic technical information on Sense-IT, including how to measure a new baseline.
Information transmission to professional	Practical information, Sense-IT manual including settings, all available information as is presented in protocol.

Step 3: Feedback during pilot with clients

The detailed version of the protocol was tested during a pilot within the inpatient addiction department of Tactus, addiction care. Testing the protocol with clients lead to additional information on strong points, but also points of improvement. The pilot phase started with three clients, who had signed their informed consent. On the second day after the introduction session, client 3 informed the psychologists in the clinic that he did not want to participate any longer. Therefore, halfway, another client was introduced to the research. The supervising healthcare psychologist suggested to include the introduction into the first session with Sense-IT in order to still receive feedback during the pilot and to synchronise all clients. However, during this session just after the introduction of the research the client politely rejected the opportunity to participate. He shared that it would be too much for him personally as an extension to the regular program. His situation was more severe in duration and substance usage compared to the other participating clients. During the pilot, Sense-IT version 2.57 was used.

In sum, two clients have finished the entire pilot. Feedback on the protocol was categorised in two different perspectives. One is from the perspective of the client, the other from the researcher and supervising health psychologist.

Feedback by clients

A description of the participating clients was already presented earlier. The two clients shared their opinion on multiple facets of the sessions. The Sense-IT itself was evaluated, but also the process and their personal situation with cravings were included.

Firstly, the feedback that was given focused on Sense-IT itself will be discussed. This aspect was not actively covered during the sessions, but it might have offered new insights for an update of the Sense-IT protocol.

Both clients experienced difficulties with the connection of the smartwatch with the smartphone. However, this was not depicted on either of the devices and resulted in confusion. This was discussed more thoroughly and solved during the first session. It was explained again how the Bluetooth connection could be refreshed manually. Furthermore, both mentioned the battery dying rather quickly, which was already a known issue by the founders of Sense-IT. In addition, they both had to get used to the delayed depiction of their own movements, especially walking. This was not the only aspect the clients had to get used to. They named the vibration itself and the colourful watch as other factors that were harder to get used to and perceived it to be challenging to ignore its distractions.

- *"You keep an eye on it, you remain mentally occupied with the smartwatch." (C1) –*

Especially one of the clients really perceived this a barrier not to wear the smartwatch. Therefore, it seemed that the period of three days to get used to Sense-IT was not sufficient. Consequently, it was decided to have the clients keep the Sense-IT in between both sessions. This was experienced as helpful, as discussed during the second session. They would have preferred to have the Sense-IT for a longer period of time before the first session with Sense-IT. However, one of the clients hardly wore the watch during the second week due to several diagnostic tests. Therefore, based on the amount of distraction it can be suggested to exclude the period of anamnesis from the Sense-IT schedule, given the distraction it may cause during the tests.

Then, feedback on the sessions itself using the protocol was given. The clients both shared that they enjoyed receiving sessions this way. They felt it was useful for them to obtain this biofeedback. During the sessions, both clients had experienced cravings caused by the guided fantasy, which they both described as being rather realistic. The training with cravings was helpful for them, since they both mentioned having difficulties in recognising these.

In addition, one of the clients mentioned that Sense-IT supported his process during other forms of therapy, e.g. PMT, as well and increased physical awareness. Also, it functioned as a catalyst for conversation with his therapist for this client. The added value as expected by the professional was in line with the real life experience of the client depicting an example of how accurately the professionals could make an estimation about their clients.

Finally, both clients already mentioned during the first session that they would like to test this outside the clinic. This was brought up by both clients without the trigger of a question. Their minds were not primed by the quality of Sense-IT, but both recognised this.

- "*Actually, I would want to test this outside the clinic. We cannot use here anyway." (C1) –*
- *"At home, this would have been completely different." (C2) –*

During the second session, both clients felt more peaceful compared to the first session. This was attributed to the fact that they already knew what was ahead of them. The videos of the discriminatory stimuli therefore did not elicit too much of an increase in heart rate. They suggested to keep the cues more realistic, nonfiction, and mentioned that the volume, which was higher during the second session, was inducing more reaction. So, volume of the cues should be taken into account as well.

Finally, the clients shared that the burden for this research was not too high and received a small thank you gift for their participation.

Feedback by supervising professional & researcher

The sessions have provided new, useful information in light of the protocol. The sessions were conducted by the researcher under supervision of one of the professionals, a healthcare psychologist. The feedback is a combination of either perspectives and is focused on the protocol.

The duration of 45 minutes per session was rather short. All sessions with both clients took almost one hour. It gave them the opportunity to evaluate on the feelings of cravings, since some of them did not have a clear view on what craving was for them. However, in the protocol there is no need to adapt that, since this extra time was spend on research related questions, which will not be a part of the eventual treatment with the protocol.

During the pilot, there was a strong deviation between the adoption of the technology when comparing both clients similarly aged. One was enthusiastic enough to volunteer for future research with Sense-IT and really experienced the added value. The other client was annoyed by the vibrations and seemed rather glad the research was finished. This level of adoption might be a larger issue with other groups of the inpatient population. The identified drivers and barriers as experienced by these two clients do provide additional insight to anticipate.

The training with the cues was rather successful. Finding the right cues was time consuming and the final idea to elicit cravings by a guided fantasy was effective. Both clients experienced cravings during this part of the session despite the fact that they did not receive those in the clinic. After the first session with the first client, it was decided to offer the discriminatory stimuli, so the video's, with more context in the form of a background story in order to elicit the same level of physical arousal. During the second session, this appeared not to be sufficient. Therefore, in the protocol this can be altered to VR or guided arousal. With VR it is easier to personalise stimuli, making it easier for clients to distinguish between arousal elicited by the two different factors.

The three days in between the introduction session and the first session was not enough for the clients to get used to the interface. Therefore, it was decided to offer the introduction session one entire week prior to the first session opposed to the three days during this pilot. During the introduction session, an anti-craving technique inventory will be created together with the client as well. This implies that the client will be asked to share which techniques are mostly used and/or most effective. In between the sessions, the clients will

keep the Sense-IT set in order to remind the client of the intervention. It is aimed to include small educational fragments in the regular program in order to stimulate awareness even more. This can be done for instance by reminding the client to rate their level of cravings and/or arousal. By reminding the client, eventually this will hopefully become an automatic thought of the client to check in on their physiological responses. The therapist can ask this during the morning reflection or during other forms of therapy in order to fully intertwine the regular treatment with this extension. Also, during the Sense-IT sessions, the client can be asked more frequently to rate the intensity of cravings, so that the client will be reminded more regularly to focus on bodily processes. Then it was also found that a clear distinction between the start and the end of the fantasy should be guarded. It was found during the pilot that it was rather hard to end the fantasy and then discuss, which can be confusing for the client. Therefore, this is a new point of attention. The end of the guided fantasy can for example be a delicate sound that reflects the ending of the fantasy. This can be a little bell or even the sound of a meditation sound scale or bowl. When the client hears this sound, he or she can open the eyes and a more rationale reflection can be started. It is important to discuss beforehand what sound the client can expect and that the meaning is explained.

Another conclusion that was made after the pilot is that the sessions with Sense-IT should be conducted independently of the regular inpatient treatment, 'Verslaving de Baas'. This was decided given the fact that this is a continuous program, making it impossible to plan the individual sessions. It was argued by the supervising health psychologist that during other sessions client will receive information on anti-craving techniques and that there was no urge to combine it with session eight of 'Verslaving de Baas' as was suggested earlier. In addition, during the introduction session it was crucial to design an inventory for all clients with useful anti-craving techniques to practise. During the sessions, this technique was mostly distraction. This is not always beneficial for the client when back at home, therefore, it was suggested to include breathing or meditation technique in order to reduce feelings of cravings. All feedback was analysed and the revised version of the protocol was created. In Table 3. an overview can be found of all major decisions per theme after the revision.

Revised version of protocol

Table 3

Overview conclusion per theme after pilot with clients

Theme	Conclusion
Added value of Sense-IT	Increases awareness on physiological processes during craving and stress/arousal.
For which clients	All clients after the detox phase without reduced intellectual capacity.
Concrete session with Sense-IT	15 minutes explaining and discussing Sense-IT and experiences with regards to cravings. 15 minutes training with cues, including guided fantasy or VR, and anti-craving techniques. 15 minutes discussing and reflecting on findings.
Amount of sessions	One introduction session, two sessions with Sense-IT all one week apart.
Preferred moment in treatment	After detox phase, not during anamnesis. Independently of the 'Verslaving de Baas' program.
Optimal duration of sessions	45 minutes per session.
Information transmission to clients	Basic information on what it is that will be done and why. Basic technical information on Sense-IT, including how to measure a new baseline. Introduction session one week before session one.
Information transmission to professional	Practical information, Sense-IT manual including settings, all available information as is presented in protocol.

Discussion

This research aimed to answer the overall research question: In what way could biocueing with the Sense-IT application be used as part of regular inpatient alcohol addiction treatment? This was done by using the objective that was formulated earlier: design a protocol for the implementation of Sense-IT into the regular addiction treatment within Tactus. The protocol was developed by answering the specific research questions. The main conclusions explained above resulted in the final version of the protocol (Attachment A). It can be concluded that the Sense-IT intervention will contain two main sessions of 45 minutes where training with cues is offered. The introduction session will be scheduled one week beforehand where all necessary knowledge concerning Sense-IT will be shared with the client. In addition, during the introduction session an inventory per client will be designed on cravings as well as on anti-craving techniques. This will all be done with the main objective to optimise training with cues in order to increase awareness on physiological processes experienced during cravings, stress and perceived emotions. Generally, this can be offered to clients who have finished their detoxification and have sufficient intellectual capacity.

In the following section, the findings will be analysed and interpreted based on existing literature. This will be done on different levels. First, the design procedure was put into perspective with the final product being known. Then, the two cycles with first professionals and then clients will be discussed individually.

Discussion/ Clinical Implications

The results depict on one hand the willingness to innovate the regular treatment, on the other hand, some practical barriers became evident that were not fully solved during the data collection. Sense-IT has not been completely implemented yet in any field, but certain pilots have been conducted, which implies that there was not an existing protocol that could be used for reference. No pilot has been conducted for Sense-IT in addiction treatment yet, making this research a legitimate addition to the existing literature. Nevertheless, a protocol can advise on how to implement Sense-IT, but this requires cooperation and support from the professionals as well as intrinsic motivation from the clients (Feijt, de Kort, Bongers, & IJsselsteijn, 2018).

The protocol was designed using the EMP framework design cycles and UCD steps. This was a new approach, as far as is found, for integrating eHealth technology into the regular treatment program. The main product that the protocol resulted in, is an intervention. This intervention is aimed at increasing emotional awareness in a timeframe of three weeks.

In the beginning of this research, it was unknown what the form of the implementation of Sense-IT would be. For instance, this could be integrated into one of the existing sessions, it could be an ambulatory treatment aspect during the entire inpatient treatment, or it could be an intervention. Analysing the integration of other eHealth tools in the current treatment, the intervention mapping method seems similar to this research. Intervention mapping is an approach for combining both empirical evidence as well as theoretical evidence by designing eHealth programs (Kok, Schaalma, Ruiter, Van Empelen, & Brug, 2004). This means that an intervention is designed based on scientific literature, existing protocols and are combined with the experience of therapists. Intervention mapping has been used for multiple eHealth interventions, including several healthcare departments and Minddistrict, which is an eHealth platform. This method is similar to the one used in this research by looking at including experience of therapists and combining that with literature. On the other hand, intervention mapping is more aimed at behavioural change, which is less of an objective for integrating Sense-IT. By comparing these methods, it appears that the method used for this research seems to be an appropriate method when the form of the integration is yet to be established.

For now, in order to fully implement the protocol in addiction treatment, a few steps are yet to be taken. This includes an analysis per design cycle before the protocol can be adopted.

First, some barriers and drivers experienced by professionals became apparent. For some of the barriers a temporary solution was found during this research. The adoption of technology is still possible even when facing certain barriers. However, it is of course desirable to overcome these barriers in order to strive to optimal adherence of the Sense-IT protocol. Nevertheless, this is a long term process and does not imply that the protocol as it is now cannot be implemented.

Firstly, the researcher was providing the sessions with the Sense-IT given the fact that the psychologists of Tactus were already quite occupied. Not enough time, physical space or priority was available for Tactus employees to conduct the sessions. This might be an issue for future usage of the protocol. It has already been indicated by previous research that innovation within mental health care is not adopted without resistance of perceived barriers (Kooij, 2019). The perceived barriers, which can generally be reduced to technology acceptance, brought up by professionals and the two clients sharing different perspectives when it comes to Sense-IT, can be explained with multiple theories such as the Unified Theory of Acceptance and Use of Technology (UTAUT), which is an update of the Technology Acceptance Model (TAM) (Venkatesh, Morris, Davis, & Davis, 2003). However,

this research utilised the LAHM Model as defined earlier in Figure 3 in order to explain certain findings.

Moreover, during the process of contacting professionals, it became evident that one of the professionals showed way more resistance to participate that others. This professional was only available for the interview and did not respond to any other email. On the other hand, one professional volunteered to supervise the sessions and provided active feedback for the final version of the protocol. Also, in the participating clients, a great difference in adoption was observed. One of the clients showed more resistance than the other client, clearly showing two different adopters. Though, these participants all were already interested in the research and enthusiastic about the plans, implying that this is a group where adoption would be less of a challenge compared to professionals and client who were asked to participate, but did not want to. Therefore, this sample of participants may not be representable adopters for the complete implementation of Sense-IT. It is common knowledge that one person might be more likely to adopt the Sense-IT protocol sooner than others as was defined already in the diffusion of innovation theory by Rogers (1962). This was also found in previous research on Sense-IT conducted at the University of Twente (Immeker, 2019; Kooij, 2019). More specifically, some professionals were tempted to sum up practical barriers. This concept can be referred to as innovation resistance (Ram & Sheth Jagdish, 1989). This resistance is exhibited during the process of accepting certain innovations while perceiving barriers. The differences in adopters of this intervention were already visible as is presented in the results. Early adopters are essential when planning future usage of the protocol, because they will practically be carrying the innovation. For instance, if some of the therapists are enthusiastic about this innovation, they might function as a social influence for their colleagues, which might result in more adoption within a mental health department (Venkatesh, Morris, Davis, & Davis, 2003).

On the other hand, all professionals held a positive attitude towards the Sense-IT and were able to describe the added value of using Sense-IT in addition to the regular inpatient treatment, e.g. an increase in awareness. These attitudes are in line with the advantages as described by the developers of Sense-IT (Derks, Visser, Bohlmeijer, & Noordzij, 2017). This implies that the intervention was understood properly and that the Sense-IT matched the needs of the professionals. Furthermore, the professionals shared the opinion that it would be beneficial to expand treatment into physiological processes rather than solely cognitive treatment.

Multiple positive aspects were found that could possibly function as facilitators during the implementation of Sense-IT in addiction treatment. For example that professionals showed an interest in this innovation.

When analysing the findings retrieved from the clients, perceived drivers and barriers were identified as well. First of all, finding clients was rather difficult. The aim was to include five clients into the current study, where only two finished. Besides the fact that the results may not be fully significant to generalise for a larger client population, this also may reflect other factors. One side effect is that this might not take as much time for the executive practitioner, which could also lead to a limited time of giving the Sense-IT sessions. This could influence the self-efficacy of the executive therapist in a negative way, due to little practise. Moreover, a relatively small client population may benefit from Sense-IT in this specific clinic. Also, this may show some inequalities among the client population in case one client is able to participate and the other one is not. Also, the fact that only two clients participated implied that a limited amount of participants were available. This could be a coincidence or this could have a particular reason. It is important to first establish whether there are enough suitable clients for this form of treatment. The definition of enough is left for the company to agree upon, Tactus in this case, since they will have to make a trade-off of expenses and added value.

Another barrier that was found during the current study is technological issues, as was already described in the LAHM model (Feijt, de Kort, Bongers, & IJsselsteijn, 2018). This was perceived when the connection between the two devices was not established properly, but this was not shown on either of them. Negative affect was caused by burden through technical problems, such as the connection that was not established at multiple times (Titzler, Saruhanjan, Berking, Riper, & Ebert, 2018). This resulted for one of the clients in frustration and reduced motivation to continue with the participation.

On the other hand, drivers became apparent during this research. The clients experienced the added value of the intervention and reckoned the training with cues to be useful in improving physiological awareness on cravings. Including this part in the regular treatment plan might result in a satisfaction of the user's needs. This can also be beneficial for the therapeutic alliance. This is already an aspects that was experienced personally by the researcher. Both clients were really open to share their stories, but also were rather grateful to have the opportunity to have individual sessions while working on awareness. This was not measured by any means, but is a subjective interpretation during the sessions.

In fact, the only issue that stands in the way of the integration of the Sense-IT into the treatment is who will conduct the sessions, since no long term solution was found yet for the limited recourses. This includes the function of the professional who could execute the intervention, but also the time dedicated to each client. This decision is also dependant on financial matters within the company, Tactus, itself. Recommendations for Tactus will be formulated in the dedicated section later on.

Strong points

This research had led to interesting outcomes, leaving a useful protocol for the utilisation of Sense-IT in inpatient addiction treatment. A strong point is that all professionals had different disciplines, making the sample rather varied. An advantage of that is that a great scale of knowledge was included in order to get as close to data saturation as possible with this number of professionals.

Moreover, this protocol contains the perspective of professionals as well as clients focussing on feasibility and optimal performance of the protocol in the first place. This holistic approach ensures that the added value for the user is optimal (Leikas, 2009).

In addition, this protocol is designed aiming to obtain a personalised protocol that is tailored to the specific eHealth technology, Sense-IT. This was found to be highly effective when looking at the adoption of the protocol (van Dooren, Visch, Spijkerman, Goossens, & Hendriks, 2020). This implies that protocol development was conducted successfully on this area, which is of high significance.

The physiological aspects of cravings have not been included in the regular treatment program yet, whereas including those could result in an increase of awareness. However, this being the first step of doing so offers a new dimension for the client to learn about the addiction. In fact, research has shown the importance of including physiological parameters in order to predict cravings and prevent relapse (Eddie, Kim, Lehrer, Deneke, & Bates, 2014; van Lier et al., 2017).

Furthermore, the guided fantasy elicited cravings successfully for both clients, making the sessions a valuable training. If cravings were not experienced by the client, the session would not have had a lot of impact on the client and the entire purpose of including these sessions would not have been met. In case this might occur in the future, some alternative future research options to induce cravings are given in recommendations paragraph.

Finally, for the current research it had been decided that Sense-IT was used in the inpatient addiction treatment of Tactus. However, Sense-IT is an ambulatory biofeedback system, which offers the most benefits in that department. However, in this research it was

aimed to increase the experience as is explained in the LAHM model and Figure 3. Having a good experience now in a safe clinical setting, might increase the behavioural intention implying that the actual use behaviour was stimulated as well. Thus, this step of opting for the inpatient treatment now, might boost the actual adoption later on making this a well- funded long-term plan.

Limitations

This research is a step into the right direction for the adoption of Sense-IT into regular addiction treatment. However, not all variables could be optimised, implying some limitation have been found during this research. Firstly, the restricting time of the research before the deadline has led to several limitations. For instance, COVID-19 limited the options in certain aspects. The interviews with the professionals could have been more efficient having a panel meeting at once with all professionals included to form ideas together. In addition, Sense-IT could have been more actively involved in that meeting informing professionals more about the options by means of a demonstration. This was now done via videocalls and descriptions. The quality of the screens was not sufficient to show clear images of the Sense-IT, making verbal descriptions the only option. The professionals might have been able to form a clearer idea on what the protocol could contain prior to be asked for their perspective if they would have gotten to know Sense-IT a bit better. Moreover, the restricting time resulted in the fact that session eight of 'Verslaving de Baas' was not included in the pilot with the clients as was intended in the first place. This was caused by timing of this session. Nonetheless, it also provided the insight of not connecting Sense-IT sessions to the regular program since that already was rather useful. This shown that even feasible options can function properly without it being the most desired option.

Furthermore, only two male clients aged similarly were participating in the pilot of which only one had a primary alcohol addiction. This does not represent the entire AUD population, making it harder to generalise the protocol. Also, the point of data saturation has not been found yet, meaning that there will be more data available that was not retrieved yet with two clients. The perspective of different age categories and female experiences for instance were not included. This is of high importance, since the technology adoption probably will be different in other population groups.

Moreover, the sessions were given by the researcher supervised by the health psychologist. This could have influenced the sessions or the perspective of the clients in a way. The fact that an outsider was asking for personal information could have made the clients feel uncomfortable. This was secured for by asking multiple times what their thoughts

were and if they felt comfortable sharing the piece of information. However, this cannot undo the fact that the researcher in fact did have an impact on the situation.

Then, a limitation with regards to the research design became evident. UCD is effective, however iteration is a large part. Due to the limited time available for this research, only one iteration in the analysis phase was possible. More iterations could be conducted in future research. Another limitation related to UCD that was already found in previous research is that users sometimes do not know yet what they would want from a future system (Olphert & Damodaran, 2002). This was clearly experienced during the interviews with the professionals. A result was that a lot of time was spent on explaining that this was a brainstorm session for an innovation. This is also a barrier that was detected earlier when using UCD (Maguire & Bevan, 2002).

Furthermore, another limitation that was discovered is with regards to privacy. During the protocol design an distinct section could be attributed to privacy of personal data. Luckily within mental health care the NIP code and other codes warrant certain aspects of privacy. However, this new technological tool does have personal information registered, making this a new topic for privacy related discussions. It should be explained clearly where the data will be stored, for how long it will be stored and what the system, Android or iOS, might do with the data (Dong, Jonker, & Pang, 2012). The information retrieved from Sense-IT might not seem tempting to have, but it is important to see beyond that. Information concerning heart rate might be of relevance for healthcare insurers for instance. Therefore, it is crucial to include research and more in- depth information to the protocol concerning the privacy of Sense-IT.

Finally, Sense-IT was designed for ambulatory biofeedback and in this study Sense-IT was opted to function in an inpatient setting. This was the first step on the way to ambulatory treatment as was discussed earlier. However, the clients both thought that these sessions with Sense-IT would be more beneficial outside the clinic, which is in line with the purpose of Sense-IT. In addition, the impact of Sense-IT cannot be fully measured until it is used completely as intended. Therefore, further steps can be taken in order to implement Sense-IT in addiction treatment, which will be discussed in the following section.

Recommendations

As a result of this research, several recommendations have been formulated. When it comes to those recommendation, a distinction can be made between future research and clinical recommendations.

Future Research

For future research it is recommended to test the protocol on a broader research sample of clients including women and other genders, different ethnicities and multiple age categories. This may provide more insights into the implementation of the protocol. Also, as shown by this research where one of the clients suffered from cocaine addiction, this may be beneficial for other clients in addiction treatment and not just for AUD.

Then, it might be needed to examine the effects on the long term. For long term adoption of the Sense-IT protocol, the consequences on the treatment plan are of importance to track (Titzler, Saruhanjan, Berking, Riper, & Ebert, 2018). Therefore, a longitudinal research including a larger sample size is of importance. This might provide insights on how and for how long the training with the cues function and remain useful knowledge for the client. For example, if the skills on recognising cravings and utilising the anti-craving techniques fade away rather soon after the session, then offering more session can be considered. Furthermore, it is interesting to measure the added value for the client. It would be interesting to conduct a quantitative research where two client groups (independent comparison groups) could be compared in treatment outcomes, e.g. long-term effectivity, by means of a chi-square test. In this comparison one group experienced regular addiction treatment and the other group used Sense-IT in addition to that. This effectivity would include where the client is now, how long the process took, how many clients relapsed and insights in own cravings for example.

Another step that can be taken is that Sense-IT can be tested using the standardised validity assessment protocol that was designed specifically for physiological signals from wearable technology based on research using the Empatica E4 wearable (van Lier et al., 2019). Including convincing psychometric properties in the protocol might enhance perceived reliability of the protocol and motivate more therapist to adopt the protocol.

Furthermore, it is recommended to extend this research into the ambulant addiction treatment. The intention of using Sense-IT for bio cueing might offer more advantages compared to only biofeedback in a clinical setting. For instance, client who almost finished their clinical treatment, could be introduced to Sense-IT while in the clinic and utilise it on an individual basis when the ambulatory treatment has commenced. The duration of the ambulatory part of the Sense-IT intervention needs more research as well in order to prevent dependency on the wearable (Derks, Visser, Bohlmeijer, & Noordzij, 2017).

In addition, ambulatory clients sometimes disappear, increasing the risk of losing materials. Thus, this guarantee of Sense-IT watches and phones could be researched.

Moreover, when it comes to recognising cravings based on physiological processes, many other factors besides heart rate could be included as a predictor of cravings. For instance, heart rate variability (HRV) or skin conductance (Quintana, Guastella, McGregor, Hickie, & Kemp, 2013; van Lier et al., 2017). These parameters can be included by means of an additional device for the biofeedback during the setting or even Sense-IT could be expanded with these functions. A future research idea might be a craving identification measuring multiple physiological processes and making the client more aware of what happens when cravings or certain emotions are experienced. Then, the Sense it could be utilised afterwards in an ambulatory setting.

Moreover, Sense-IT offers a lot of potential benefits to this group of clients. It can be considered which other client groups can be helped with this innovation. Sense-IT had been tested in the field of Borderline Personality Disorder and in the department of aggression regulation. It can be examined whether Sense-It can be beneficial for clients with other addictions. The participants of the current study were already distributed in substance, implying that this intervention could be utilised for all Substance Use Disorders (SUD). In addition, emotional dysregulation is a known issue for clients with PTSD as well, making this an interesting field for future research (Weiss, Tull, Viana, Anestis, & Gratz, 2012). Also, it has been found that emotion regulation difficulties enhance the risk of developing depression or bipolar disorder (Heissler, Kanske, Schönfelder, & Wessa, 2014; Kanske, Schönfelder, Forneck, & Wessa, 2015). So, other mental disorders can be included for a pilot with Sense-IT.

Finally, research into an updated version of Sense-IT can be conducted. In this update, the objective would be to make the watch visibly less obtrusive. In addition, battery duration and connection could be optimised. Furthermore, the movement detector could be evaluated, since the biocues were already given prior to the movement detection. During the sessions, many measurements were needed, however, in the regular day to day life these might have been too many. This worked on the nerves of the client in this study and could have influenced their perspective on Sense-IT. A suggestion would be to be able to install these settings in a timeframe rather than manual over the course of the day. Here, it is meant to offer the option to set an alarm for instance on the vibrations. For instance, the client always wakes up around 7.00 am and gets ready, which could imply walking stairs. Then, it might be a solution to install that vibrations will not be offered at all during 7.00 and 8.00 am. This is something that is already possible. However, this has to be adapted manually. A sort of time schedule where the therapist can pre-install this with the client during a session, would be

helpful in reducing those frustrations. If cravings were to be experienced during that time, the smartwatch would still depict the increase in heart rate. Moreover, the smartwatch is not necessarily optimised with regards to privacy. The clients shared that other clients asked about their increased heart rate, because they were able to see the smartwatch perfectly. Perhaps a more modest or simpler design could offer less visibility to outer groups and facilitate privacy.

Clinical Practice

With regards to clinical practice there are two different approaches, one being focused on recommendations with the means that are available now and the other being more general recommendations.

With the current, revised protocol a step can already be made for implementing Sense-IT. However, the main barrier as retrieved from this research is that there are limited time resources on offering individual sessions. Therefore, this is a step that first needs to be overcome and a consensus has to be made on who will execute the sessions. On the other hand, the protocol seemed to have achieved something for both clients, which is eliciting craving and analysing what physiological processes are related to that for them on an individual basis. Moreover, the perspective of clients were not much different as those from the professionals meaning not many conceptual and fundamental changes have been made after the pilot. Also, it is recommended to test for adherence when the protocol is used by therapists in order to reassure if the protocol and Sense-IT are used properly.

It would also be recommended to arrange a workshop provided by universities or trainings institutes at the start of the protocol implementation. During these workshops all professionals might learn more concerning Sense-IT and the protocol, and might feel more prepared for offering the sessions themselves.

When it comes to the recommendations in the clinic, cues could be presented using VR in order to improve the experience during cue reactivity and facilitate embodiment as discussed in one of the interviews with professionals. In addition, personalising cues is easier. More research into the effectivity of VR and feasibility of including equipment in order to raise the level of arousal is needed.

On a more general note, it is recommended Tactus assigns an ambassador the task to warrant the proper implementation of Sense-IT and to stimulate innovation. In addition, this person can be the emergency contact of the Sense-IT sessions, which can be added to the protocol. At this point, there is a person working on the implementation of eHealth within Tactus. Including Sense-IT in this initiative, could be useful as well as assigning one or two

people to carry the responsibility per department. The professionals per department could function as innovator and facilitate social influence by pitching Sense-IT in an attractive way in order to stimulate adoption as was explained earlier.

For now, it would be recommended to offer this extension to clients who are highly motivated to participate. This might imply a smaller group of clients on whom the effectivity and long term effects can be tested. Finally, the ambiguity of who might execute the sessions is left for Tactus to rearrange their resources and make company specific decisions.

Conclusion

This study resulted in a deeper understanding of the fact that Sense-IT can be integrated in the existing alcohol addiction treatment on an intervention basis. The protocol was evaluated to be functioning and only little adaptions were made after the pilot. Both clients and psychologists recognised the potential of further developing the designed protocol. This implies that a usable protocol is as good as ready to adopt is the result of the current study in the field of addiction treatment. It was shown that Sense-IT could be implemented in the addiction treatment if the practical time resources are evaluated. In addition further research into long term effects is needed.

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Appendix A

Sense-IT

Instructie hulpverlener voor de inzet van de Sense-IT app gedurende klinische opname

Inleiding

Dit is de instructie voor hulpverleners m.b.t. het gebruik van Sense-IT[2] binnen de reguliere, klinische behandeling van cliënten met een stoornis in alcoholgebruik. Hierin staat beschreven wat Sense-IT is, voor wie het gebruikt kan worden en welke stappen genomen moeten worden samen met de client om Sense-IT te kunnen toevoegen aan de bestaande behandeling. Gedurende de pilot fase zal de onderzoeker de taken van de hulpverlener overnemen.

Sense-IT app

Wat is het?

Sense-IT is een ambulant biofeedback systeem op basis van hartslag en kan mogelijk helpen bij het vergroten van het emotionele bewustzijn van trek en de lichamelijke reacties daarop. Het cognitieve en fysiologische bewustzijn is vaak laag bij mensen met een stoornis in alcoholgebruik. Dit is een probleem, omdat dit factoren zijn die bijdragen aan het bestaan van de stoornis. Op het moment wordt er binnen de verslavingszorg weinig aandacht besteed aan de fysiologische reactie en het gebrek aan emotionele bewustzijn van trek. Het is echter aangetoond dat deze factoren cruciaal zijn voor het herstel van cliënten binnen deze groep (Berking et al., 2011; Petit et al., 2015). Biofeedback kan het bewustzijn van trek vergroten om zo het herstel te bevorderen. Gebruik van de Sense-IT in de reguliere klinische behandeling kan daarom van toegevoegde waarde zijn.

Hoe werkt het?

Sense-IT bestaat uit een smartwatch en smartphone waarop de applicatie Sense-IT is geïnstalleerd. De app is voor zowel Android als IOS beschikbaar. Op de smartwatch zijn bolletjes te zien die de variatie in hartslag ten opzichte van een baseline hartslag aangeven. Met behulp van een nulmeting wordt deze baseline hartslag vastgesteld. In de gebruiksaanwijzing in de bijlage staat beschreven hoe deze nulmeting uitgevoerd kan worden. Je kunt bolletjes (van -3 tot 5) zien op je horloge die jou iets vertellen over de hoogte van je hartslag. Feedback kan ook worden gegeven door de smartwatch in de vorm van een trilling. Je kunt zelf instellen bij welk ‘bolletje’ het horloge gaat trillen. Het vierde bolletje is je baseline hartslag. Als je minder bolletjes hebt dan vier is je hartslag dus lager dan tijdens de nulmeting. Als je meer dan vier bolletjes hebt is je hartslag hoger. Als je merkt dat het horloge

[2] De Sense-IT app is ontwikkeld door Scelta, Universiteit Twente, VUmc en Arkin.

heel vaak veel bolletjes laat zien, kan het zijn dat je nulmeting niet goed is gegaan of dat je het horloge wat minder gevoelig in moet stellen. Dit ‘instellen’ van de Sense-IT is erg belangrijk en op die manier zorg je dat de Sense-IT nog beter bij de client past.

Voor wie?

Sense-IT is geschikt voor cliënten met een primaire alcohol verslaving. Echter, voor gebruik van andere middelen kan Sense-IT ook ingezet worden. Voor cliënten met een neurologische aandoening, epilepsie niet passend bij middelen gebruik, cardiovasculaire aandoening of medicijn gebruik, wordt het aangeraden om op individuele basis te overwegen of de client deel kan nemen aan deze interventie. Daarnaast is basis kennis van technologische tools, zoals een smartwatch en smartphone, wenselijk. Basis kennis houdt in dat de client zonder begeleiding in staat is om de Sense-IT set te bedienen. Verder is gebleken dat cliënten met een beperkte intelligentie moeite hebben met het begrijpen van de sessies. Ook hiervoor moet door de behandelaar per individu een inschatting maken of de client wel of niet geschikt zou zijn voor deze aanvulling.

Stappenplan

INTRODUCTIE SESSIE

De client ontvangt de Sense-IT set 7 dagen voor eerste sessie om hieraan te wennen en krijgt hierbij een uitgebreide uitleg over Sense-IT. Een uitgebreide versie hiervan zal de client in de vorm van een informatieve brief ontvangen om na te lezen en is te vinden op pagina X. Tijdens de introductie sessie zal tevens een nulmeting worden gedaan onder begeleiding van de hulpverlener waarbij de client zoveel mogelijk een realistische hartslag en variatie van die hartslag heeft. Een realistische hartslag is een hartslag en variantie die op dagelijkse basis representatief is bij de client in verschillende (sociale / werk) situaties. Dit is van belang, om te verzekeren dat de biofeedback relevante signalen geeft. Verdere instellingen van de Sense-IT kan de hulpverlener samen met de client bepalen. Meer informatie hierover is te vinden in de handleiding van Sense-IT op pagina X van deze instructie.

De voorbereiding van het aanbieden van cues start met een cue identificering. Dit houdt in dat er tijdens de introductie sessie per client gekeken zal worden welke cues het meest geschikt zijn. Maak hierbij een inventaris van de drank, die de client het liefst drinkt, op welke plek, welk moment, met wie, etc. Tijdens het aanbieden van de cues wordt er in beide sessies een geleide fantasie gedaan waarbij deze informatie gebruikt kan worden. Daarnaast worden er 2

discriminerende of spannende cues aangeboden in de vorm van een video. De spannende cues bestaan uit een video met een schrikelement en een video waarbij de spanning wordt opgevoerd. Alle cues worden voorlopig digitaal gepresenteerd, omdat zo de diversiteit aan cues gegarandeerd kan worden. Voor de toekomst kan presentatie van cues via Virtual Reality een optie zijn om de belevenis wereld te vergroten. Tevens zouden realistische cues kunnen worden aangeboden. Om met digitale cues zoveel mogelijk effect te kunnen bereiken zorgt de hulpverlener tijdens de training ervoor dat de aandacht van de client maximaal gericht is op de cue en dat vermijding voorkomen wordt. Hierbij kan rekening worden gehouden met het volume van de video's. Als het volume te zacht is, kan de client minder intense spanning in het lichaam ervaren wat het moeilijker maakt om daarna te onderscheiden.

Vervolgens wordt een inventaris gemaakt van anti-craving technieken per client. Hierin worden afspraken gemaakt welke technieken de client prettig vindt en welke in de Sense-IT sessies geoefend kunnen worden.

SENSE-IT SESSIE

Na de introductie sessie vinden er twee Sense-IT sessies plaats. De sessies worden individueel aangeboden en vinden in twee achtereenvolgende weken plaats. In het reguliere Verslaving de Baas programma wordt er gewerkt met anti-craving technieken, die vervolgens verder getraind kunnen worden met behulp van de Sense-IT.

De duur van beide sessies is ongeveer 45 minuten.

De hulpverlener wordt gevraagd om de algemene teksten in deze instructie aan te passen aan de persoonlijke situatie van elke client.

Beide sessies hebben globaal dezelfde indeling:

- Uitleg van de sessie
- Het blootstellen aan cues
- Het bespreken van de ervaringen

Sessies met de Sense-IT

Cue exposure

Programma:

- Kennismaking Sense-IT (sessie 1) / bespreken vorige sessie (sessie 2)
- Uitleg van de sessie
- Aanbieden van cues
- Training anti-craving technieken
- Bespreken ervaringen

Start van de sessie of bespreken ervaringen

Alleen tijdens sessie 1: Bespreken eerste ervaringen met het gebruik van de Sense-IT, gedurende de week waarin de Sense-IT reeds werd gedragen. Het doel van deze week is om de client te laten wennen aan de biosensor en biofeedback die gegeven wordt door de smartwatch. Vraag tijdens de bespreking bijvoorbeeld:

- *Wat de client van de Sense-It vindt tot nu toe en waarom.*
- *Of de client trek heeft ervaren in de afgelopen week en of dit zichtbaar was op de smartwatch.*
- *Of/hoe de Sense-IT impact heeft gehad op het dagelijkse leven de afgelopen week.*

Uitleg sessie

Bespreek wat er in de sessie gaat gebeuren en leg uit waarom. De toegevoegde waarde van Sense-IT, zoals uitgelegd op pagina 2, kan hierbij gebruikt worden. Het doel van de Sense-IT sessies is dat de client in een vertrouwde omgeving kan oefenen om trek beter te kunnen herkennen en leert hoe het best gehandeld kan worden met de mentale en fysieke trek om zo terugval in de toekomst te voorkomen. Een voorbeeld van de uitleg van de sessie kan zijn:

> *Vandaag gaan we trek opwekken door middel van een geleide fantasie en video's die ik je ga laten zien. Hierdoor zou het kunnen dat je hartslag hoger wordt, maar natuurlijk wordt je hartslag niet alleen hoger met trek, dit kan ook door andere dingen komen. Als je hartslag heel veel hoger is dan normaal, zal je van de smartwatch een trilling krijgen. We willen weten of dit bij de geleide fantasie over alcohol anders is dan bij spannende video's zonder alcohol. Als je hartslag hoger is door trek gaan we oefenen met de zelfcontrole technieken, die je geleerd hebt tijdens Verslaving de Baas.*

Je krijgt 2 video's te zien, die spannende elementen hebben en de volgende video begint pas als de hartslag weer lager is. Het is erg belangrijk dat je je goed concentreert op de video's en je je niet laat afleiden. Daarnaast doen we een geleide fantasie. Hierbij gaan we proberen om jou terug te plaatsen in een oude situatie waarin je gebruikte. Ik wil je vragen om aan ons alles wat je ziet, hoort, proeft, ruikt, etc. te beschrijven. Hoe beter je nu oefent, hoe makkelijker je er later mee om kunt gaan. Het is heel belangrijk om goed om te kunnen gaan met trek, omdat trek kan leiden tot terugval. Trek op zich is ook niet erg om te ervaren, als je maar weet hoe je er voor jezelf het beste mee om kunt gaan. Dit verschilt per persoon en daarom willen we dat nu vast oefenen.

Denk je dat je het aan kunt om nu trek te ervaren? (Zo niet: dan is het juist belangrijk om er nu mee te oefenen).

Heb je voor we beginnen nog vragen en/of opmerkingen?

Ben je er klaar voor om te beginnen? Aan het begin en het einde van de geleide fantasie zal ik deze bel zachtjes laten afgaan. Dit is voor jou een teken dat de fantasie alleen hiertussen plaats vindt. Daarna mag je rustig je ogen open doen als je er klaar voor bent en gaan we bespreken wat je ervaren hebt.

Aanbieden cues

Vraag voor de cue exposure begint of de client trek aan kan op het moment dat het tijdens de sessie op komt. Maak het bespreekbaar en leg uit hoe belangrijk het is om de trek te ervaren om anti-craving technieken te kunnen trainen.

Concreet zal het aanbieden van cues en de training met de anti-craving technieken per cue gaan. De client wordt blootgesteld aan de eerste cue of geleide fantasie. Er wordt gekeken welke informatie de smartwatch hier over geeft. Informeer hoeveel trek de client ervaart op een schaal van 0 (geen trek) tot 10 (zeer erge trek). Leg hierbij uit dat trek ook ervaren kan worden als de trek wordt weerstaan. Oefen samen met de client een anti-craving techniek, die eerder aangeleerd is bij Verslaving de Baas, en houdt in de gaten wat er gebeurt met de hartslag en met de trek van de client. De volgende cue wordt pas aangeboden op het moment dat de hartslag weer het punt van de nul meting heeft bereikt en de trek is gedaald. Maak het bespreekbaar wat de client voelt in het lichaam, laat de client omschrijven wat er gebeurt en

hoe lang dit duurt. Vraag wat de client heeft gemerkt bij het toepassen van de anti-craving techniek.

Herhaal dit tot de cues gepresenteerd zijn. Neem aan het einde van de cue exposure met de client door wat de ervaringen en bevindingen van de sessie zijn. Vraag hierbij of de client fysiek verschil heeft gemerkt tussen de alcohol-gerelateerde geleide fantasie en discriminerende cues, wat de client er van vond om dit op te wekken en wat deze sessie de client geleerd heeft.

Voorbeeld vragen zijn:

- *Heb je trek ervaren tijdens de sessie?*
- *Zo ja, wat deed de trek met je? Welke gedachten en gevoelens had je?*
- *Wat vond je er van om deze trek op te wekken?*
- *Heb je een verschil gemerkt in je reactie tussen de cues met alcohol er in verwerkt en de andere cues?*
- *Welke anti-craving techniek vond je het meest/ minst prettig om toe te passen? Waarom?*
- *Wat heb je deze sessie geleerd?*

De Sense-IT set wordt tussen de sessies door gehouden door de client. Huiswerk wordt niet meegegeven, maar cliënten worden gevraagd om bij een trilling hun spanningsniveau en de oorzaak van de verhoogde hartslag bij te houden.

Referenties

Berking, M., Margraf, M., Ebert, D., Wupperman, P., Hofmann, S. G., & Junghanns, K. (2011). Deficits in emotion-regulation skills predict alcohol use during and after cognitive–behavioral therapy for alcohol dependence. *Journal of Consulting and Clinical Psychology, 79*(3), 307-318. doi:10.1037/a0023421

Petit, G., Luminet, O., Maurage, F., Tecco, J., Lechantre, S., Ferauge, M., . . . de Timary, P. (2015). Emotion Regulation in Alcohol Dependence. *Alcoholism: Clinical and Experimental Research, 39*(12), 2471-2479. doi:10.1111/acer.12914

Appendix B

Titel van het onderzoek
De ontwikkeling van een protocol voor het gebruik van biosensor Sense-IT bij de behandeling van een stoornis in alcohol gebruik.

Inleiding
Geachte heer/mevrouw,

Wij vragen u vriendelijk om mee te doen aan een onderzoek bij Tactus Verslavingszorg. U beslist zelf of u wilt meedoen. Voordat u de beslissing neemt, is het belangrijk om meer te weten over het onderzoek. In deze informatiebrief vertellen wij u meer over het onderzoek. Lees deze informatie rustig door. Heeft u na het lezen van de informatie nog vragen? Dan kunt u contact opnemen met Marlon Rouw, de onderzoeker. Onderaan deze brief staat haar email adres vermeld.
Via uw eigen hulpverlener bent u benaderd met de vraag of u aan dit onderzoek wilt deelnemen. Het onderzoek zal uitgevoerd worden op de Tactus-locatie aan de Raiffeisenstraat in Enschede.

1. Wat is het doel van het onderzoek?
Met dit onderzoek willen we de behandeling van een stoornis in alcoholgebruik verbeteren voor de toekomst. We gaan meten wat er gebeurt met uw hartslag als u in aanraking komt met zaken die met alcohol te maken hebben. We willen weten of uw hartslag dan verandert doordat u trek krijgt. Dit meten we met een smartwatch die u om uw pols kunt dragen. We gaan dus kijken wat trek doet met uw lichaam en hoe u daar op reageert. Het doel is om te zorgen dat u dat later beter kunt herkennen en er naar kunt handelen. In het grote geheel gaan we dus onderzoeken hoe Sense-IT het best ingezet kan worden als onderdeel van de reguliere klinische behandeling. Daarbij is het belangrijk om te onderzoeken wat de meerwaarde van Sense-IT precies is. In het kader daarvan hebben we een interventie ontwikkeld, die we u, als client, graag willen laten ervaren, zodat u hierover de mening kan geven. We willen graag dat cliënten met ons meedenken in dit ontwikkelproces, zodat toekomstige cliënten hier eventueel later mee geholpen kunnen worden.

2. Hoe wordt het onderzoek uitgevoerd?
Als u mee wilt doen, vragen we u twee maal deel te nemen aan een individuele therapie sessie. De onderzoeker is aanwezig om onder begeleiding van de coördinerend ggz psycholoog de sessies met de Sense-IT uit te voeren. Tussen de twee sessies zit ongeveer een week. Eén sessie duurt in totaal drie kwartier. U krijgt drie dagen voor de eerste sessie een volledige uitleg van de onderzoeker over de app, zodat u de tijd heeft om te wennen aan de Sense-IT smartwatch en smartphone. Aan het einde van de laatste sessie zal u gevraagd worden uw ervaring te delen, zodat we deze kunnen meenemen in de verdere ontwikkeling van het protocol?

3. Wat betekent het onderzoek voor u?
U heeft van uw hulpverlener deze informatie over het onderzoek ontvangen. Hij of zij vraagt u of u interesse heeft om deel te nemen. Wanneer u akkoord gaat met deelname zal de hulpverlener of onderzoeker in overleg met u de afspraken inplannen. Deze vinden plaats op de locatie Raiffeisenstraat 40 in Enschede. Wij vragen u voorzichtig om te gaan met de Sense-IT smartwatch en telefoon, die u zult ontvangen. Deze blijven te allen tijde eigendom van Universiteit Twente.

4. Wat gebeurt er als u niet (meer) wilt deelnemen?
Als u besluit aan het onderzoek deel te nemen, kunt u zich altijd bedenken en toch stoppen. U hoeft dan geen reden te geven waarom u wilt stoppen. U beslist zelf of u mee wilt doen aan het onderzoek. Wel of niet meedoen heeft voor uw behandeling geen gevolgen.

5. Wat gebeurt er met uw gegevens?
Voor dit onderzoek worden uw persoonsgegevens gebruikt en bewaard volgens internationale regels en wetten. Alleen de onderzoekers en de Inspectie voor de Gezondheidszorg mogen uw onderzoeksgegevens inzien. De gegevens worden tot 5 jaar na het einde van het onderzoek bewaard. Daarna worden ze vernietigd.

6. Wilt u verder nog iets weten?
Voor het stellen van vragen over het onderzoek kunt u voor, tijdens en na het onderzoek contact opnemen met de onderzoeker (m.rouw@student.utwente.nl).

Bedankt voor uw medewerking!

Met vriendelijke groet,

Marlon Rouw
Onderzoeker
Bijlagen
A: Toestemmingsformulier

Bijlage A Toestemmingsformulier

Toestemmingsformulier
Meting van het gebruik van biosensor Sense-IT bij de behandeling van een stoornis in alcohol gebruik:
Versienummer: 1 Datum: 10 juni 2020

Ik heb de informatiebrief voor deelname aan het onderzoek gelezen. Ik kon aanvullende vragen stellen. Mijn vragen zijn genoeg beantwoord. Ik had genoeg tijd om te beslissen of ik meedoe.

Ik weet dat meedoen helemaal vrijwillig is. Ik weet dat ik op ieder moment kan beslissen om toch niet mee te doen. Daarvoor hoef ik geen reden te geven.

Ik weet dat sommige mensen mijn gegevens kunnen zien. Die mensen staan vermeld in de informatiebrief.

Ik geef toestemming om mijn onderzoeksgegevens 5 jaar na afloop van dit onderzoek te bewaren.

Ik wil meedoen aan dit onderzoek.

Naam deelnemer:

Handtekening: Datum : __ / __ / __

Ik verklaar hierbij dat ik deze deelnemer volledig heb geïnformeerd over het genoemde onderzoek.
Als er tijdens het onderzoek informatie bekend wordt die de toestemming van de deelnemer zou kunnen beïnvloeden, dan breng ik hem/haar daarvan tijdig op de hoogte.

Naam onderzoeker (of diens vertegenwoordiger):

Handtekening: Datum: __ / __ / __
