



UNIVERSITY OF TWENTE.

**Acceptance and
Potential Clinical
Added Value of Sense-
IT in Forensic
Psychiatric Patients
with ASD and/or ID: a
Proof-of-Concept Study**

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Abstract

Background: Everyone knows the feeling of increasing anger or arousal and the difficulties with self-control resulting from it. For people with an Autism Spectrum Disorder (ASD) and Intellectual Disabilities (ID) this is even harder, because their ability to recognize and interpret arousal is impaired. This leads to a disproportionate representation of this group in prison and forensic care. The ambulatory biofeedback technology Sense-IT aims to encourage emotional awareness. In order to develop an intervention that targets this inability a proof-of-concept study with Sense-IT in forensic inpatient care was conducted.

Objective: Aims of the study are to (1) establish possible necessary adaptations to the software and the research design in order to run a more elaborated controlled trial, (2) to detect obstacles regarding the technology, (3) to find a trend whether the level of aggression is positively affected by the use of Sense-IT aggression and (4) to examine the system usability of the Sense-IT app.

Methods: This proof of concept study was designed as a mixed methods approach with semi structured interviews and three different questionnaires. The study was conducted with five participants suffering from ASD and ID, who were treated at FPA de Boog in Warnsveld. The approach consisted of 30 of baseline measurements of heart rate and 14 days of intervention.

Results: One out of five participants benefited from the technology as evidenced by the results of SDAS-9. Overall the System Usability of Sense-IT was rated quite positive. However, participants experienced a substantial amount of obstacles during the interventions with Sense-IT.

Conclusion: The use of ambulatory biofeedback via an eHealth technology is a good possible approach in order to target the problem of this specific patient group regarding their inability to estimate their own emotion. Yet, Sense-IT is not working properly with respect to connection and synchronization and participants experienced some obstacles. Adaptions have to be made especially regarding the accuracy with which Sense-IT measures feelings and regarding synchronization. A next version of Sense-IT will most likely improve people's satisfaction with the technology. It could further be of interest to test Sense-IT with autistic people beyond a forensic setting.

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Introduction

The speed and complexity of our world and society is ever increasing. With this increasing complexity the need rises for a strong distinct understanding of those structures and capable executive functions. Two mental disorders which are often associated with a certain lack in these cognitive skills are Autism Spectrum Disorders (ASD) and Intellectual Disability (ID). Charman (2002) found prevalence rates of 6.0/1.000 for ASD. In the past the diagnostic boundaries of the core presentation of autism have been broadened, which leads to increased prevalence rates over the decades (Charman, 2002). A similar increase can be found for Intellectual disability. In a Meta-analysis of 52 studies Maulik et al. (2013) found prevalence rates of 10.37/1000 for ID. There has further been evidence that people with Intellectual Disability are overrepresented among suspects in interviews by police and in prison populations in many western jurisdictions (Hayes, 1997). Such an overrepresentation in the legal system also accounts for people with ASD. Anckarsäter et al. (2018) found rates between 2,4% and 5,3% for autistic people being among subjects in forensic psychiatry and special youth centers. A reason for such high rates might be the inability of people with these disorders to analyze and regulate their emotional experiences, which is one of the main reasons for undesirable and aggressive behavior (Cohen, Yoo, Godwin & Moskowitz, 2011; Groden, Baron & Groden, 2006; Janssen et al., 2002; Lunenborg, 2013; Picard, 2009; Silani et al., 2008). Treatments regarding this group of patients mainly consist of psychoeducation, cognitive behavioral therapy (CBT) and pharmacological treatments (Binnie & Blainey, 2013; Singh, Lancioni & Sing, 2011; Spain, Sin, Chalder, Murphy, & Happe, 2014). The current popularity and wearable self-tracking trends enable a unique opportunity for a new type of intervention. Therefore, researchers of the University of Twente developed an application and a corresponding smartwatch, called Sense-IT, which provides people with ambulatory biofeedback (Derks, De Visser, Bohlmeijer & Noordzij, 2017) in order to better estimate their emotional arousal. The aim of the current proof-of-concept-study is to examine the feasibility, acceptance and potential added clinical value of the Sense-IT application within a forensic setting and patients with ASD and ID. It is expected to collect information about the willingness of the participants to wear the application and their experiences with it. Furthermore, specific information will be collected about factors that have to be adjusted in order to run a full study.

To obtain deeper understanding of how biofeedback can help people with ASD and ID regulate their emotions, it is important to understand what and ASD and ID diagnoses include and how they affect emotional experiences and a higher aggression potential. ASD is

characterized by persistent deficits in social communication and restricted repetitive patterns of behavior, interests or activities (DSM-5; APA, 2013). ASD results from an early altered brain development and neural reorganization (Baumann & Kemper, 2005; O'Reilly et.al., 2017). To be diagnosed with ASD a person must show evidence of difficulties, past or present, in social- emotional-reciprocity, non-verbal communicative behaviors and in developing, maintaining and understanding relationships. Furthermore, there must be abnormalities in the form of restricted, repetitive patterns of behavior, interests or activities. This includes stereotyped or repetitive motor movements, use of objects and speech, insistence on sameness to routines, highly restricted, fixated interests that are abnormal in intensity and focus. In addition, people with ASD often show a hyperreactivity and hyporeactivity to sensory input (Lord, Petkova, Hus et.al. 2012; Männer, Rice, Arneson et.al. 2014; Weitlauf, Gotham, Verhorn, Warren, 2014). People who suffer from ID show deficits in intellectual functioning that include reasoning, problem solving, planning, abstract thinking, judgment, academic and experiential learning (DSM-5; APA, 2013). Furthermore, they show deficits or impairments in adaptive functioning which is needed in order to live in an independent and responsible manner. Skills that emerge from adaptive functioning are communication, social skills, personal independence at home or in community settings and school or work functioning (DSM.5; APA,2013). A symptom that both disorders have in common are difficulties in emotional-reciprocity, which is dispositive for the development of aggressive behavior. Aggressive behavior may in this context serve as a way to modulate physiological emotional activity (Cohen et al., 2011; Guess & Carr, 1991), which leads to the fact that people with ASD and ID disproportionated often happen to end up in prison or forensic inpatient care.

One method, that targets the lacking skill of both disorders to become aware of physiological responses due to unconscious emotional states, is biofeedback. Biofeedback in psychotherapy is used as “a treatment technique in which people are trained to improve their physical and/or mental health by using signals from their own bodies.” (Dinut, 2017). A central component of many interventions that aim to reduce aggressive behaviour, is training people to become more aware of their own body and to recognize signs of arousal (Goldstein et al., 1987; Robertson, Daffern, & Bucks, 2012). The ability to recognize and also describe internal emotional experiences is considered essential in order to receive access to the adaptive functional information in the emotion (Gohm & Clore, 2002; Greenberg et al. 2007). Being able to recognize what the emotion is signaling can help people behave according to these needs (Robertson, Daffern & Bucks, 2012). Berkowitz (1990) even suggests that when

people become highly aware of their aroused feelings, they pay more attention to possible causes and appropriate responses to what they feel, which leads to increased self-restrained and less unhelpful behavior. Thus, limited information originating from the emotion often makes it difficult to show helpful reactions, which either bring people with ID and ASD into jail or keeps them there. The current state of the art is that people have to recognize bodily sensations such as changes in heart rate and breathing on their own through effortful introspection. However, these signs are easy to miss (Lunenborg, 2013). A method that can be helpful to avoid that, is using ambulatory technology, which means that the user constantly wears a smartwatch that is connected to an app. This way of ambulatory biofeedback provides the user with constant monitoring and feedback of bodily sensations without distracting him and can give information that selective biofeedback cannot provide.

A technology that utilizes the benefits and facts regarding ambulatory biofeedback is the Sense-IT application. Sense-IT consists of two components: A smartphone application and a smartwatch. The smartphone functions as a diary in order to record possible anomalies. The app is connected to a smartwatch, that the user constantly wears and that measures his heart rate. When the heart rate reaches a certain level, the user receives a tactile and visual feedback in form of vibration and bubbles that appear on the smartwatch monitor. This way the user receives direct and explicit information about significant rises in heart rate above predetermined, personalized baseline levels and associated boundaries. This form of bio-cuing information only indicates personalized high values, that alert the user when changes occur. Thus, users are encouraged to read and interpret biofeedback themselves by engaging in self-reflection (Yu, 2018).

The Study

The technology has already been piloted within patients diagnosed with a borderline personality disorder and their therapists (Derks, De Visser, Bohlmeijer, & Noordzij, 2017) and in college students (Spitzer, 2019). Similar to a borderline personality disorder people with ASD and ID suffer from impairments in their ability to recognize changes in their emotion. This inability to cope with emotional stress makes it necessary to develop a treatment that targets the problem of emotion regulation thus, body awareness.

The present study aims to answer a set of research questions in order to determine obstacles in feasibility and acceptance of Sense-IT. Furthermore, it aims to determine the potential added clinical value that this particular technology may have for this specific area of patient treatment. The proof-of-concept character of this study emphasizes the possibility to

acknowledge any kind of information that arises. Since the existing body of research with ambulatory biofeedback is small, Sense-IT in this context functions as an open research tool.

More specifically the study seeks to investigate in detecting limitations of the technology. Through the explorative character and by means of the System Usability Scale, a tool for rating the general system usability of a technology (Brooke, 1996) and the interviews, information about the general usability of smartwatch and application are gathered. According to the CeHRes Roadmap, a guide to develop e-Health technologies (Gemert-Pijnen, Kelder, Kip & Sanderman, 2018) e-Health development is intertwined with implementation and the process requires continuous evaluation cycles (Gemert-Pijnen, Kelder, Kip & Sanderman, 2018). This way the gathered information will be used to further refine Sense-IT. Beyond that the study aims to detect a positive relationship between the daily use of Sense-IT and a decreasing potential of aggression. Thus, the following questions will be answered throughout the study:

1. 'What are general experiences with system usability that have to be adapted in order to run a full study?'
2. 'What kind of limitations did patients experience using Sense-IT?'
3. 'To what extent is a trend visible regarding a minimized potential of aggression?'

Methodology

Study design

The Sense-IT study is a proof-of-concept study in which Sense-IT is integrated as a part of inpatient treatment at FPA De Boog, GGNet. A proof-of-concept (PoC) study in a medical context is defined as a clinical trial carried out to determine if a treatment is biologically active or inactive (Lawrence, 2005). In terms of Sense-IT this implies examining the effectiveness of the technology in order to redirect resources more productively within a randomized controlled trial. FPA De Boog is a forensic care setting in Warnsveld and part of the GGNet, which is considered an association of professionals in the field of psychology. Adult psychiatric patients with ASD and ID, who committed a crime are often referred to this

setting. FPA De Boog is one of the few settings in the Netherlands that offer forensic treatment for these patients.

The study was designed as a mixed methods study conducting questionnaires and interviews with open questions. Mixed methods research is defined as the integration of quantitative and qualitative research in order to best address the research problem (Plano Clark & Ivankova, 2016). This way well-validated conclusions can be developed by gaining information obtained from a quantitative survey with thematic results obtained from qualitative interviews. If the results from the different methods are in compliance, researchers can be more confident in what they have found (Plano Clark & Ivankova, 2016). Qualitative studies are used to emphasize an interpretive approach that both poses and resolves research questions (Kaplan & Duchon, 1988). In line with this is the significant value to assess perception, perspective and lived experience of participants. Quantitative research on the other hand is often used to further refine already very narrow and well-studied constructs or to test strong and pre-determined hypotheses. Therefore, qualitative research can generate novel insights into phenomena which are broader and more difficult to measure quantitatively (Marshall, 1996). By using a mixed methods design it was possible to substantiate participants' quantitative assessment of Sense-IT and its usability by statements of the interviews. This way, a connection between scores and perceptions could be established.

Materials

Different kind of materials were involved in the study. For the research different hardware such as smartwatches and smartphones were used. Furthermore, the software Sense-IT application was consulted. For data collection the researchers made use of semi structured interview questions, the System Usability Scale (SUS), the Client Satisfaction Questionnaire (CSQ) and the Social Dysfunctional Aggression Scale (SDAS-9).

Hardware. Smartwatches and smartphones were provided by the University of Twente. The smartwatch is by the manufacturer TICwatch E from Mobvoi or the Huawei Watch 2 by Huawei and runs with a version of "WearOS". Smartphones are from the manufacturer Nokia with android 7.1. To get started the smartwatch has to be connected to a smartphone that necessarily had to be supported by the Android operating system. To connect the two devices the application "WearOS" had to be installed on the smartphone. In order to complete the

process, a GPS-signal had to be activated on the smartphone and the devices could connect via Bluetooth or Wi-fi.

To measure the heart-rate a non-invasive manner of photoethismography (PPG) was used, which is a technique to detect blood volume changes in the microvascular bed of tissue. This particular technique is often used to make measurements at the skin surface (Allen, 2007).

Software. The Sense-IT software was developed by the University of Twente in collaboration with GGNet-Scelta, VUmc, Arkin and Pluryn. Goal of the software is to make emotional arousal visible in order to learn how to deal with it appropriately. The app is designed in the Dutch language. For the installation of the app it is required to open a web-link, which comes with a handbook that explains all necessary steps of the installation process. The figure below shows the start screen of the application.

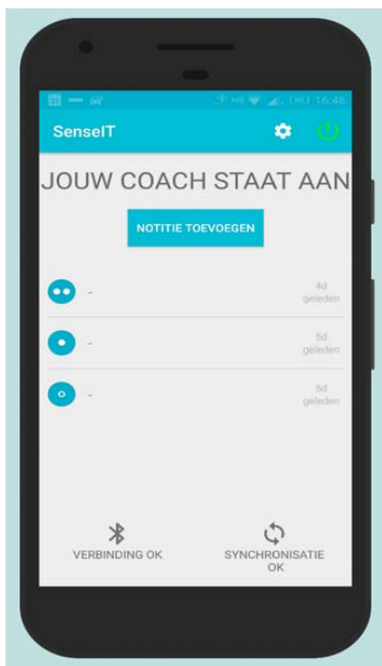


Figure 2. Start Screen

The Sense-It part of the smartphone gives insight into the measurements that have been taken. On the upper right side are two buttons. One is the switch-one button and the other one is leading to the setting-menu. The symbol on the left down side shows whether the smartphone is connected with the watch. The symbol right next to it displays if the data is synchronized. In order to open the setting menu a password has to be entered.

On the smartwatch side the Sense-IT standalone software displays the heart rate measured by the watch itself on a scale from 1 to 10. During the first use of the watch, an individual mean

baseline heart rate and standard deviation during rest is determined. After that a threshold criterion is established for informing users of rising and falling heart rates. The user is visually and optionally tactile informed of this change via the watch, which serves as a monitor to become aware of eventual changes in arousal and heart rate. These changes are visualized on the monitor in the form of bubbles that pop up and multiply when the heart rate of the user increases. The bubbles disappear and lessen whenever the heart rate drops. The picture below shows the Sense-IT smartwatch and its method of heart rate visualization.



Figure 3. Sense-IT Smartwatch

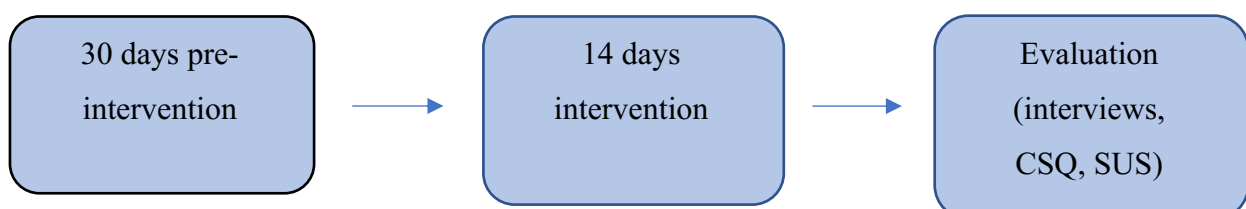
Questionnaires. Overall, three questionnaires have been used. The one that was used within the research phase was the Social Dysfunction and Aggression Scale (SDAS-9), which functioned as a tool to measure the development of the level of aggression. Caretakers had to fill in the SDAS-9 for each participant at the end of every day within the research phase. The SADS-9 consists of 9 items with 7 items covering outward aggression and 2 items covering inward aggression (Wistedt et al., 1990). Within this questionnaire caretakers had to rate items like irritability, dysmorphic mood, verbal aggression and physical violence on a 4-point scale from not present to severely present. The SDAS-9 was carried out in Dutch language. After the completed research phase participants had to answer the System Usability Scale (SUS) in order to examine possible usability issues that affected the seamless use of the system. This tool consists of 10 items with five possible response options that range from strongly agree to strongly disagree. Exemplary items are “I found the system unnecessarily complex” or “I felt very confident using the system”. The SUS makes it possible to evaluate different products and services such as hardware, software, mobile-devices, websites and

applications (Brooke, 1996). Another questionnaire that was conducted after the research phase is the Client Satisfaction Questionnaire (CSQ) for assessing general satisfaction with services. The CSQ offers 4 different response options ranging from excellent to poor on items like “To what extend has our program met your needs?” or “How would you rate the quality of service you received?”. Both the SUS and the CSQ where conducted in Dutch language.

Interviews. The interviews were carried out in Dutch language. All interviews were conducted by the responsible researcher right after the 14-days research period ended and before the use of the SUS and CSQ. The interviews are designed in a semi-structured way. Semi-structured interviews are well suited for the exploration of perceptions and opinions of participants regarding complex issues (Barriball & While, 1994). Yet, they offer enough standardization in wording that any differences in the answer are due to differences in the respondents rather than in the questions asked (Gordon, 1975). The open questions provide an opportunity for the participant to emphasize his unique experience with the technology which leads to a comprehensive overview that displays individualized positive and negative user-feedback around theoretical assumptions and points of interest that the researcher has identified being most relevant. Furthermore, open questions avoid the misguiding of respondents in a certain direction.

The 12 open questions (see Appendix A: interview schema) mainly refer to usability and personal experiences of the participants with the Sense-IT application and particularly experiences with use and wear of the smartwatch. The first five questions deal with general impressions of the Sense-IT smartwatch and refer to situations in which the technology was considered helpful or disturbing. The two following questions refer to the perception and what the user was thinking when the smartwatch did or did not match his actual feelings. In question eight the researchers want to know whether participants would recommend the technology to another person or not. Question nine and ten target the user’s feeling regarding the vibration mode and the arising bubbles on the monitor as a sign for emotional arousal. How visible have the bubbles been and what does the participant think of these functions? The last two questions are a little bit more general and refer to the look of the watch and whether there are any further comments that the participant would like to add.

Procedure



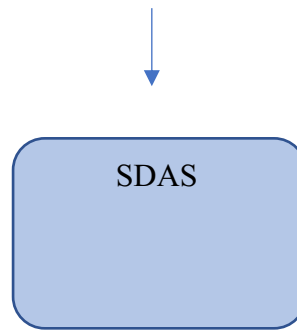


Figure 1: Research design

The study consisted of three phases (see Figure 1 above), which are the pre-intervention phase, the main intervention phase and the evaluation phase.

In the beginning, all inpatients from FPA De Boog were considered potential participants. Thus, all of the patients from these wards have been informed over aim and purpose of the study and received a short demonstration of the Sense-It application. None of the eligible participants had a therapeutic relationship to the principal investigator. After the presentation, interested participants received an information letter and informed consent form. A week from that they were asked whether they are willing to participate in the study. In case of confirmation, participants had to sign the informed consent in order to give permission to the responsible clinician, who was also responsible for checking inclusion criteria and possible security risks.

Starting point of the study was a “set-up day” and a “test-day”, where participants were instructed in the use of Sense-IT and where the baseline measurement took place. During the “test-day” participants had the opportunity to test different types of feedback (visual or tactile) from the smartwatch and the different types of thresholds. Furthermore, the Social Dysfunction and Aggression Scale (SDAS-9) was conducted by the caretakers every day, in order to measure the pretest level of aggression. After setting up the technology, participants wore the smartwatch for 14 days. After a week the principal investigator checked whether participants needed additional support or if any questions were remaining. In order to collect information about the development of the aggression level, caretakers were asked to fill in the SDAS after each day of wearing the Sense-It technology. The day after the 2-week study period participants have been interviewed about their experiences with Sense-IT. Therefore, a semi structured interview with 11 questions was used. The interviews were audio-only recorded and have been manually transcribed and coded. In addition to that, the System

Usability Scale (SUS) and the Client Satisfaction Assessment (CSQ) were conducted to collect information about feasibility and usability issues of the technology. Participants, who completed the interview and questionnaires received a compensation in the form of vouchers worth 20€, regardless of the actual use of the Sense-IT smartwatch and smartphone. This means that patients could abstain from wearing the smartwatch during the study and still collect their reward by being part of the evaluation. This is a typical approach in forensic setting, where such conditions are needed, to prevent participants from signing up and dropping out solely to collect compensation. Also, information from participants who stopped using the Sense-IT wearable can provide important insight regarding the future of the technology.

Participants

Recruitment of participants for the study took place within the inpatient care at FPA De Boog, GGNet in Warnsveld. To participate, patients had to be diagnosed with ASD and/or ID according to DSM-5 criteria. Furthermore, they needed to be mentally competent and willing to participate in the study. Patients that were unable to read or speak the Dutch language were excluded. Another exclusion criterion was the use of beta-blockers. All patients from FPA De Boog are potential participants and have been informed on the aim and purpose of the study.

The final study consisted of 5 participants in total, four men and one woman. All participants were of Dutch origin. Their ages ranged from 26 to 63 with a mean of 36,2 years (SD=13,64). Four of them were suffering from an Autism Spectrum Disorder and one from an Intellectual Disability.

Because of the explorative character of the study such a small sample size is sufficient in order to make statements about the feasibility of this proof-of-concept study.

Data analysis

All interviews were transcribed by the researcher. The transcriptions were analyzed with the program "Atlas.ti." The analysis was made based on the research questions. The analysis of the interviews was also made per research question. In order to do so, different codes were used. On the basis of grounded theory, which is a technique with general guidelines for gathering and analyzing data that aims to code data and integrate it into theoretical categories (Strauss & Cobin, 1997), an inductive approach was used. That means that there was no underlying structure or theory in order to build the categories. Accordingly, a structure was examined based on the build codes and categories (Glaser & Strauss, 1967).

In order to answer the first research question results of the SUS and the CSQ were taken into account. The SUS can be scored via a coding system. For the items 1,3,5,7 and 9 the score contribution is the scale position minus 1. For the items 2,4,6,8 and 10 the contribution is 5 minus the scale position. To obtain the overall value of the SUS, the score was multiplied by 2,5 (Brooke, 1996). The resulting score is a value between 0 and 100. The quality of the system usability is considered “low marginal” with a score above 50 and “high marginal” with a score above 62. With a score above 70 the system usability is “passable” (Bangor, Kortum, & Miller, 2008).

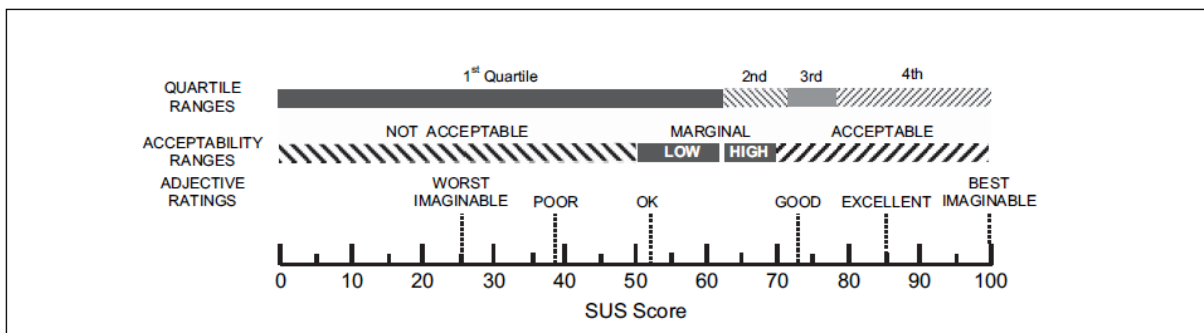


Figure 4. Subdivisions of the quality of the SUS Score (Bangor, Kortum, & Miller, 2008).

An overall score of the CSQ is calculated by summing the respondent’s rating score for each scale item. Scores range from 8 to 32, with higher values indicating higher satisfaction.

In order to determine a tendency of the effectiveness regarding potential for aggression a visual analysis of graphic displays has been made, where data is graphed for each participant during a study with trend, level and stability of data assessed between conditions (Lane & Gast, 2013)

To analyze the correlation of different factors such as obstacles, usability quality and aggression in order to examine feasibility and conception of the study, a single subject approach was used (Mehl & Matthias, 2011). This approach enables the researcher to receive a comprehensive picture of every single participant and to contextualize outcomes of the different measurements.

Results

Data was collected for each participant, transcribed and manually sorted in SPSS and Excel. Missing values were noted. The results will be presented in the following section. In order to get a better understanding of the data, each participant will be briefly introduced.

Descriptive Statistics

In order to receive a comprehensive overview, the characteristics of participants were summarized in a Table 1. The outcomes of the SUS and the CSQ were calculated and presented in Table 2.

Table 1: Participant characteristics

| | SI-101 | SI-103 | SI-104 | SI-105 | SI-108 |
|-----------------------------------------------|---------------|---------------|---------------|---------------|---------------|
| Age | 63 | 26 | 33 | 32 | 27 |
| Gender | m | f | m | m | m |
| DSM-5 Diagnosis | ASD | ID | ASD | ASD | ID |
| Aggressive beha- vior in the past | no | yes | yes | yes | yes |
| Senteced for aggressive delict | no | yes | yes | no | yes |

Participant SI-101

Participant SI-101 was a 63-year-old man. He was not known for showing any aggressive behaviour and was not sentenced because of an aggressive delict. Participant SI-101 was diagnosed with pedophilic disorder, exhibitionistic disorder and Autism spectrum disorder. He further has problems related to legal circumstances and has moderate intellectual disabilities. His non-aggressive behaviour is also reflected in the outcomes of the SDAS-9. His level of aggression was constantly rated with 0. Therefore, his highest and lowest score was 0. Mean score in the preintervention and the intervention was 0. There are no trends visible.

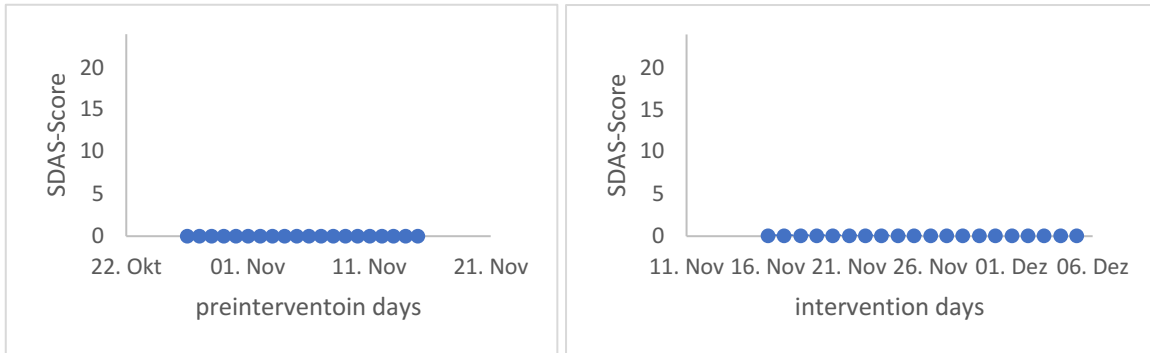


Figure 5. SDAS-Score SI-101

Participant SI-103

Participant SI-103 was a 26-year-old woman. She regularly showed aggressive behaviour in the past and was also sentenced for an aggressive delict. She suffers from a brief psychotic disorder, an alcohol dependency and a cannabis use disorder. She was further diagnosed with unspecified drug dependence and use and a moderate intellectual disability. Participant SI-103 barely showed any aggressive behaviour. Her highest score was a 2 on the second day of the preintervention, which makes a mean score of 0,1 with a SD of 0,39. Within the intervention days wearing Sense-IT her behaviour was slightly more aggressive ranging from 0-3 with a mean score of 0,53 and a SD of 1,04.

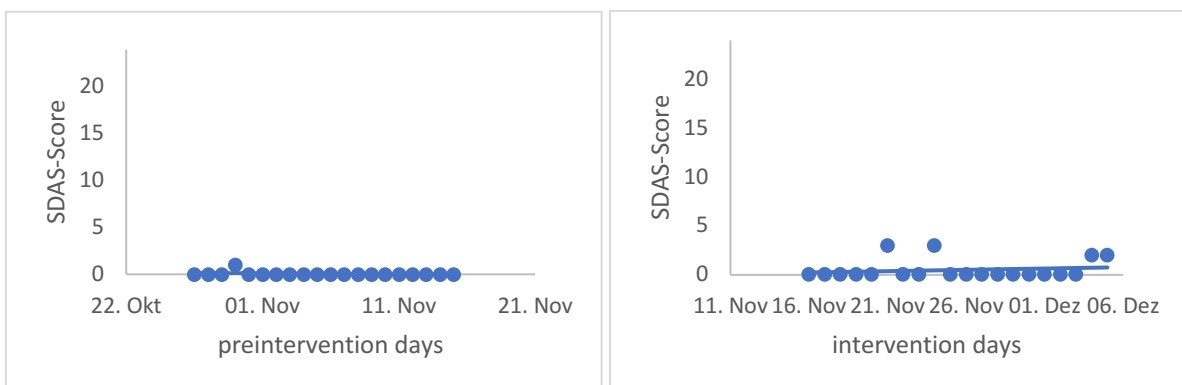


Figure 6: SDAS-Score SI-103

Participant SI-104

Participant SI-104 was a 33-year-old man who was already known for showing aggressive behaviour. He was further sentenced for an aggressive offence. He was diagnosed with Autism spectrum disorder, cannabis use disorder, an unspecified amphetamine and other psychostimulant dependence. In addition to that he suffers from an alcohol use disorder and a

psychotic disorder. The fact that the participant showed aggressive behaviour in the past, is also represented in the outcomes of the SDAS-9. Within the preintervention days his level of aggression was rated on a range from 0 to 10 with a mean of 1,59 and a SD of 2,57. During the intervention his highest score was 11 with a mean of 2,16 and a SD of 3,19 and a slightly decreasing trend at the end of the intervention.

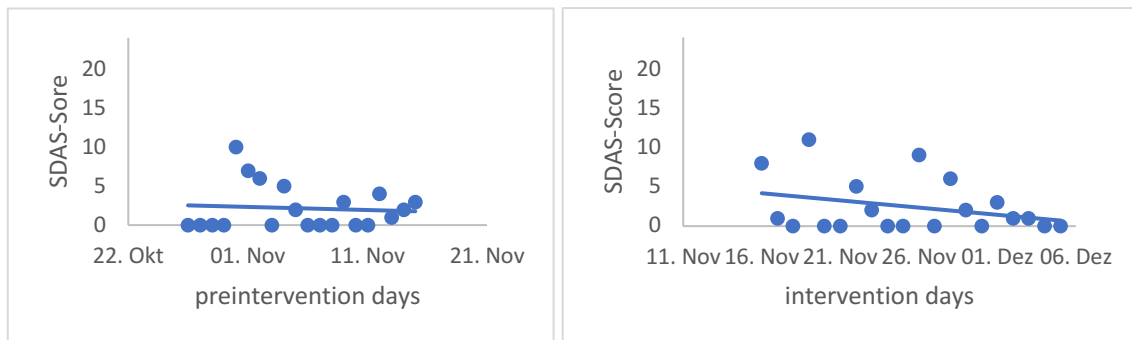


Figure 7: SDAS-Score SI-104

Participant SI-105

Participant SI-105 was a 32-year-old man who was sentenced for an aggressive offence and regularly shows aggressive behavior. Next to an autism spectrum disorder he was also diagnosed with cocaine and cannabis use disorder, social maladjustment and acculturation problems. The results of the SDAS-9 are consistent with the previous perception of the participant. Within the 30 days of preintervention he regularly showed aggressive behavior ranging from 0 – 24 with a mean of 6,23 and a SD of 4,55. Within the 14 intervention days wearing the Sense-It application he showed increased aggressive behavior with a lowest score of 2 and the highest score of 17 and a mean of 8,26 with a SD of 7,48. His scores of the SUS and the CSQ in order to evaluate the technology are missing.

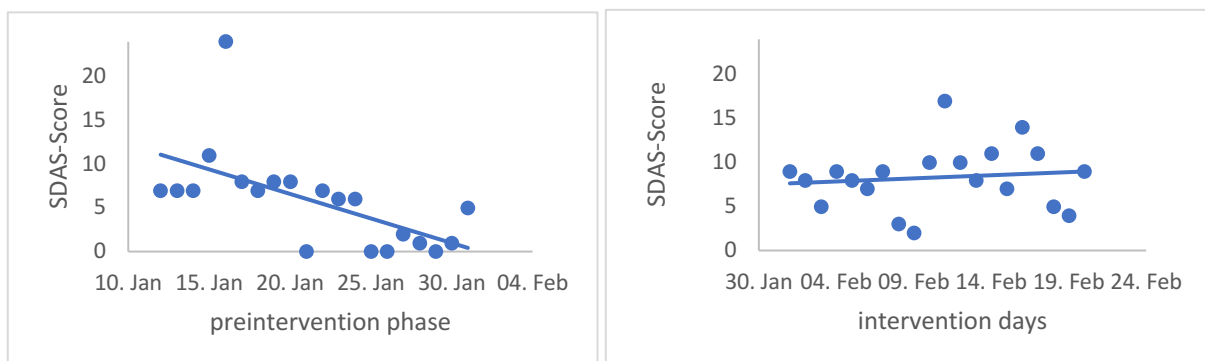


Figure 8: SDAS-Scores SI-105

Participant SI-108

Participant SI-108 was a 27-year-old man. He was sentenced for an aggressive offence and was also known for showing aggressive behavior in the past. He was diagnosed with an undifferentiated schizophrenia, an autism spectrum disorder, cannabis abuse and dependency and alcohol use disorder. In addition to that he suffers from obesity, had problems with legal circumstances as well as occupational circumstances and maladjustments. His level of aggression during the 30 days of preintervention was rated with a highest score of 5 and a mean score of 1,73 and a SD of 1,61. During the 14 days of preintervention his highest score was a 6 at the end of the intervention. His mean score within this time was 0,82 with a SD of 1,54. Therefore, his level of aggression was lower wearing Sense-IT than without the technology.

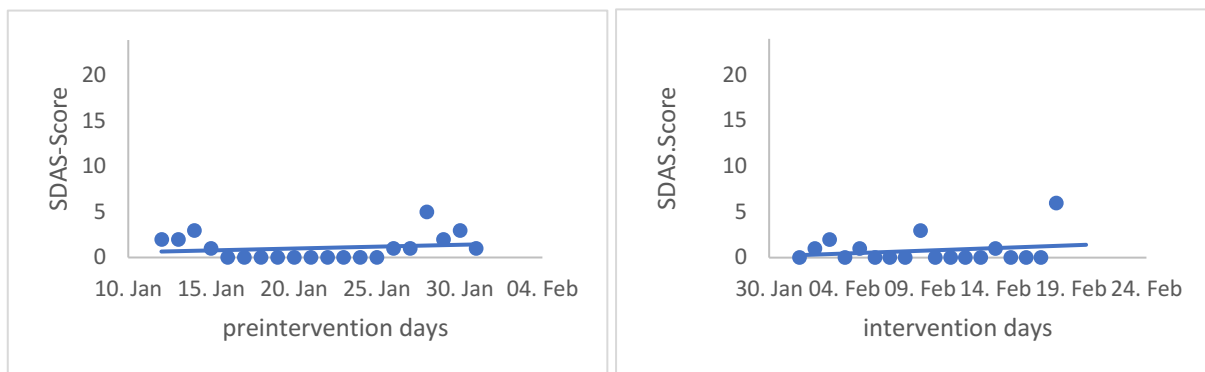


Figure 9: SDAS-Scores SI-108

To receive a comprehensive overview of the outcomes of the SDAS-9 within the preintervention days and the intervention days, mean scores and standard deviation per participant are summarized in Table 2.

Table 2. Summary of Means and SD's per participant regarding the SDAS-9

| | SI-101 | | SI-103 | | SI-104 | | SI-105 | | SI-108 | |
|-------------|--------|----|--------|------|--------|------|--------|------|--------|------|
| | M | SD | M | SD | M | SD | M | SD | M | SD |
| Pre | 0 | 0 | 0,1 | 0,39 | 1,59 | 2,57 | 6,23 | 4,55 | 1,73 | 1,61 |
| post | 0 | 0 | 0,53 | 1,04 | 2,16 | 3,19 | 8,26 | 7,48 | 0,53 | 1,04 |

System usability

The single scores of each participant regarding both questionnaires are shown in Table 3. They are further visually presented in Figure 10 and 11. The single SUS-scores of each participant are shown in Figure 10. The green bar marks the limit, where a technology is considered passable. According to the SUS participants evaluated the technology very similar. The scores of participant SI-105 are missing. The analysis of the SUS gave a Total SUS score of 74,376 which is considered as good quality.

Single scores of the CSQ are presented in Figure 11. In contrast to the SUS, the satisfaction with the technology was rated lower. The overall score of the CSQ is 19,5. With higher scores indicating higher satisfaction, this score can be classified as ok. The Scores of participant SI-105 are missing.

Table 3. SUS-Score and CSQ-Score

| | SI-101 | SI-103 | SI-104 | SI-105 | SI-108 | M |
|------------|--------|--------|--------|---------|--------|------|
| SUS | 75 | 65 | 72,5 | missing | 85 | 74,4 |
| CSQ | 22 | 19 | 19 | missing | 18 | 19,5 |

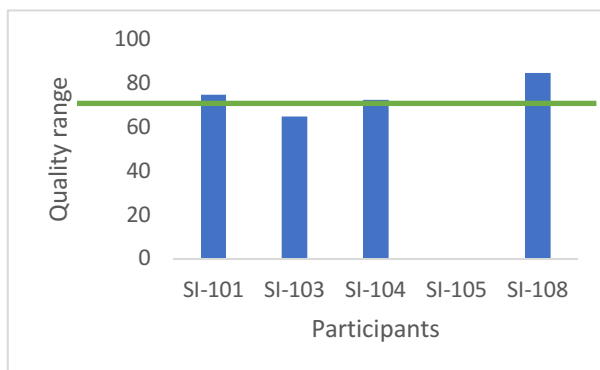


Figure 10. Single SUS scores of the participants with the limit for a passable valuation (green bar)

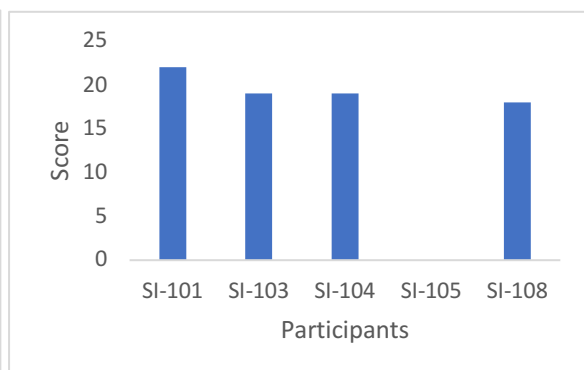


Figure 11. Single CSQ scores

The first research question investigates in general experience with Sense-IT and therefore adaptations that have to be made in order to run a full randomized controlled trial. In the following table different themes, that occurred are summarized, that occurred throughout the interviews as suggestions for improvements.

Table 4. Number of cods per participant regarding improvements

| Code | Definition | 101 | 103 | 104 | 105 | 108 | Total |
|---------------------|---------------------------------------------------------------------|-----|-----|-----|-----|-----|-------|
| Improvements | Things that have to be Improved | | | | | | |
| General Function | improvements for the general functioning Of the technology | 2 | 0 | 1 | 0 | 0 | 3 |
| Optic | improvements regarding Appearance of phone, smartwatch and software | 1 | 0 | 1 | 0 | 0 | 2 |
| Battery | improvements regarding Battery charge | 0 | 1 | 1 | 0 | 0 | 2 |
| Vibration | improvements regarding Vibration mode | 0 | 0 | 1 | 1 | 1 | 3 |
| Other | suggestions for improvements that are not assignable | 2 | 0 | 1 | 1 | 2 | 6 |

A)

General function

Suggestions for improvements regarding the general functioning of the technology were mentioned by 2 participants with 3 statements. The participants were of opinion that the technology did not work properly and needs to be more finetuned. They would only recommend Sense-IT, after improving the function of the technology.

I: Would you recommend Sense-IT! to other people? Why?

P: That depends on whether it works properly or not. You have to further test it. (SI-101)

P: Yes, certainly when Sense-IT is more finetuned. (SI-104)

B)

Optic

Another theme that occurred throughout the interviews was the appearance of the smartphone, software and the smartwatch. Multiple participants perceived the size of the smartphone as too big and considered it as difficult to carry it around, particularly because they were using

their private smartphone at the same time. They further suggested, that it could be helpful to have colored bubbles on the smartwatch and also a colored background. One participant stated that he would like to be able to make adaptations regarding the color on his own and have more opportunities for personal variation within the settings. Apart from the critiqued aspects of the visualization and the size of the phone, it was mentioned that the participants did like the aesthetics of the smartwatch and even got compliments for it.

P: I would like to have a more colorful background and also colored bubbles. I think it would be nice if we could vary more. (S-101)

C)

Battery

The third theme that has been identified as a suggestion for improvement was with regard to battery life of phone and smartwatch. Throughout the interviews statements have been made over the battery life of the phone, because it required a daily recharge, when it was used to the amount that the study intended. Two participants stated that they would enjoy a longer battery life, in order to cut down from charging the phone daily. Similar statements occurred regarding the smartwatch. Since participants were wearing the smartwatch all day the battery current consumption was high and the smartwatch had to be charged every day. Participants perceived the frequent need to recharge the items as disturbing and suggested a longer battery life in order to make wearing the smartwatch more comfortable and less burdensome.

P: I think it is annoying that I have to recharge the watch every day. I would like to have a longer battery life. (S-103)

D)

Vibration

Another theme that was mentioned is related to the vibration mode, that in a tactile manner shows the users when their heart rate has risen. Participants could optionally choose whether they wanted a tactile signal or not. Three participants made statements about the vibration mode throughout the interviews. Participant SI-108 perceived the length of the vibration signal as too long. In line with that is the statement of another participant, who criticized the frequency with what the smartwatch vibrates. For people that feel irritated quickly a high frequented signal seemed to be disturbing. However, another user stated that he could well notice the vibration but it did not distract him and he would like to have it somewhat harder.

Nevertheless, some other participants mentioned that they are satisfied with the way that the tactile signal works.

P:(...) The vibration did not distract me, but I could well notice it. It could have been harder sometimes. (SI-104)

P: (...)If 'it would vibrate every half hour, it would also be annoying if you get irritated quickly. (SI-105)

E)

Other

The category „Other“ includes all statements that contained important suggestions for adaptations but that were only mentioned once and could not be assigned to another category. The listed statements often occurred with regard to the interview question, whether participants had any leftover comments that were not covered by any preceding questions. Subsequent to becoming aware of arousal participants needed to engage in strategies in order to cope with it. One participant suggested to add an intervention to the study in order to adequately learn how to relax in case of high arousal. Furthermore, it has been elaborated that one user saw it as an advantage to have the application constantly open in order to easily have access to it. In one case Participant SI-104 mentioned that he would like to extend the baseline meeting of the heart rate. As matters stand in this study the baseline meeting took place during the “set-up” day and lasted a couple hours. It was suggested to extend the baseline meeting to preferably one weekend or at least one entire day, to receive a valid representation of the baseline. Although the pedometer is not a required function for the study, participants deprecated the accuracy of it.

Generally, participants evaluated the visualization of changes in heart rate by means of the bubbles as positive. However, one participant stated that he would have preferred to have a graph, that features the development of arousal.

P: I think that the baseline meeting has to be longer. Preferably one weekend or at least one day. (SI-104)

The second research questions asked for limitations that patients experienced during the intervention using Sense-IT. The number of statements per participant regarding these different kind of obstacles that users came across are summarized in Table 4.

Table 5. Number of codes per person regarding obstacles

| Code | Definition | 101 | 103 | 104 | 105 | 108 | Total |
|----------------------------|------------------------------------------------------------------------|-----|-----|-----|-----|-----|-------|
| Obstacles | Things regarding the technology that did not work properly | | | | | | |
| Synchronization/Connection | problems with synchronization and connection | 3 | 0 | 0 | 2 | 0 | 5 |
| Accuracy | discrepancy between Estimates arousal and estimation of the technology | 4 | 0 | 2 | 1 | 2 | 9 |
| Handling | problems with handling of the technology | 0 | 1 | 0 | 1 | 0 | 2 |
| Technical Problems | problems regarding the technique of phone and smartwatch | 0 | 0 | 3 | 0 | 0 | 3 |

A) Synchronization/Connection

A theme that has been identified as a limitation are synchronization and connection. Sense-IT works with Wifi and Bluetooth. Presuming that these connections are lost it can be considered that Sense-IT cannot keep track of his function. This has been confirmed throughout the interviews. With 5 statements this theme was mentioned frequently. To start with, participants reported that Sense-IT often got stuck and did not react. One participant stated that he did indeed experienced a feeling of arousal, but due to lost connection Sense-IT did not pick that up. It further became apparent that Sense-IT only works with a proper Wi-fi connection. This seemed to be a problem within a forensic treatment environment. Participants mentioned that there was often no wireless connection available, which made working with Sense-IT impossible.

P:(...) I really liked Sense-IT but it did not always work properly and often got stuck. (SI-101)

B) Accuracy

The category Accuracy refers to the discrepancy with which the technology depicts the heart rate of the participants. Most of the statements that were made by the participants referred to this category and almost all of the participants experienced that Sense-IT did not depict their arousal accurately. Four out of nine statements within this category contained critiques about the amount of bubbles not correlating with their experienced arousal. Two participants report that they experienced confusion when Sense-IT showed an increasing amount of bubbles, thus increased heart rate, that did not match their own estimation of arousal. In addition, it was mentioned that the watch started to vibrate without any reason. One participant further explained that Sense-IT already reacted on small movements and tiny tension, so that it did not adequately depict what the participant was doing and therefore created confusion. Another participant reported that his heart rate was inappropriately low while doing fitness, thus the photoplethysmographic measurement via skin conduction did not seem precise enough.

P: (...) tension in my head was in my opinion not observed by Sense-IT. A couple times I experienced stress and slight irritation and I got a maximum of one bubble. (...) (SI-104)

C) Handling

Another theme that occurred throughout the interviews referring to handling of Sense-IT. This refers to usability of the technology associated with daily engagement, more precisely easy and comfortable use. Participants wore the technology constantly every day in different situations. Thus, the smartwatch was constantly visible for everybody and so are the bubbles that occur, when the heart rate rises. Participants reported that they felt uncomfortable when the bubbles became visible and people were asking about them. It was further expressed that the smartphone was too heavy for daily use and that it was not convenient to carry it around easily in the pocket of a jacket or pants. According to some of the participants that made engaging in the daily use of Sense-IT harder.

P:(...)I think it was annoying that the bubbles have been visible for others because they were asking for them. (SI-103)

D) Technical Problems

The fourth theme that has been identified are technical problems. Within this category statements are captured that deal with problems regarding the technique during the

intervention. Three Participants did experience technical problems. One was for example that the monitor of the smartwatch did not turn on immediately. They further reported that it took some time until the watch gave feedback. Another statement was that the overview on the phone screen happens to move not adequately and that it got stuck from now and then, so that it was impossible to further scroll down.

Discussion

This proof- of- concept study set out to explore how people with ASD and ID in forensic inpatient care experience Sense-IT and whether it has a positive effect on their emotion regulation, thus their aggressive potential. The findings have shown that Sense-IT in its current state has some limitations and does not affect the aggressiveness of people. Nevertheless, participants enjoyed using ambulatory biofeedback und rated usability overall positive. Below further elaboration will be provided on these findings, limitations of the study and implications for future research.

Firstly, to provide an answer to the first research question and thus to analyze the general system usability of Sense-IT and adjustments that are required to run a full study, outcomes of the CSQ and the SUS appeared to be of great importance. In addition, all subcodes that are abstracted from the code “improvements” contribute to the analyzation of this question, which will be evaluated in the following. According to the SUS participants experienced the general system usability overall as good. From the items it becomes clear that participants were able to use the technology without any help and rated the use as easy an uncomplicated. In contrast, the satisfaction with the technology can be considered lower. Only half of the participants mentioned that Sense-IT could help them with their symptoms and would continue using it. In line with these findings is the amount of codes that could be abstracted with regard to possible improvements. In order to further improve the satisfaction with Sense-IT in the future, adjustments referring to general function, optic, battery and vibration have to be made. Furthermore, the need for more variation and personalization of Sense-IT was a striking finding throughout the codes. These results reflect those of Lentferink et al. (2017), who stated that personalization of technical features is important for the commitment of an eHealth intervention. It is further striking that participant SI-108, who as the only one seemed to benefit from Sense-IT, also has the highest score within the SUS. The second highest score was reached by participant SI-101, who was not affected at all by Sense-

IT. These outcomes indicate that a good system usability correlates with a higher effectiveness of the technology. This is covered by the outcomes of a study of Chan and Kaufmann (2011). They found out that a range of access, resources, and skills barriers prevent health care consumers from fully engaging in and benefiting from the spectrum of eHealth interventions (Chan & Kaufmann, 2011).

To answer the second research question subcodes regarding to obstacles are taken into account. Findings of these study show that Sense-IT does have some limitations, which are regarding to synchronization/connection, accuracy, handling and technical problems. Most striking is the accuracy with which Sense-IT is measuring the heart rate of the user. It seems like Sense-IT has problems with measuring the users heart rate precisely. The technology frequently happened to give a signal when participants were at a resting pulse. Or It depicted a rather low heart rate when a participant was working out. This can be related to the so-called baseline problem. Nakasone, Prendinger and Ishizuka (2005) introduced this specific problem and refer to it as a problem of finding a condition against which physiological change can be compared – the baseline. They stated that an obvious choice is a “rest” period where the subject can be assumed to have no emotion. However, emotion is rarely superimposed upon an induced state of rest (Nakasone, Prendinger & Ishizuka, 2005) but it most typically occurs when the organism is in some prior activation. The developers of Sense-IT could benefit from this knowledge by adjusting the technology or the study set up by adopting a baseline procedure that generates a moderate level of ANS activity. Kleiger et al. (1991) found out that measures of heart rate variability are stable over a short period of time. Therefore, taking a relatively stable short period of time baseline measurement as a standard of comparison might not have been the best choice. An implication for future research could be to extend the baseline procedure in order to receive a more valid reflection of the average heart rate. That could lead to less fluctuations and discrepancies of Sense-IT measuring heart rate.

Thirdly to provide an answer to the last research question, findings have shown that, based on the outcomes of the SDAS-9, the integration of biofeedback into the daily life of this specific group of patients in forensic inpatient care does not positively affect their ability for emotion regulation. These findings are controversial to what has been expected beforehand. One explanation for these inconsistent outcomes is that participants might have experienced the extended attention to their body as a burden, which lead to mentioned confusion and anger. According to Fairclough (2009) the constant use of physiological computing technology exposes the user to a parallel representation of emotional experiences. That leads to an impaired self-experience. For people with ASD and ID, who are not used to be

confronted with body awareness and self-reflection, a constant exposure to own body signals, could have been overwhelming. For future research this implies to further investigate in depth in how a long-term use of wearable biofeedback technology affects self-perception.

Another reason for these controversial findings could be the choice of the target group. It is indeed the case that people with ASD and ID often suffer from a reduced ability of own body awareness. Nevertheless, did some of the interview questions seem to provide insight into personality traits of the participants. Some of them stated that they would recommend the technology to people, who have problems with becoming aware of own body signals and arousal. It was obvious that they don't associate themselves with this group of people and that they do not see Sense-IT as a helpful supplement for their own. This may result from impaired executive functions that underlie many functional deficits associated with ASD (Henninger & Taylor, 2012) and thus little understanding of own disease. Michalak & Schulte (2002) stated that the failure of an intervention correlates with deficits in motivation and a negative anticipated outcome of the therapy. Thus, a narrowed understanding and reflection of own symptoms may have decreased the motivation to fully engage into the current study.

Strengths and Weaknesses

To start with the strong points of this research, the length of the study should be acknowledged. There have been more than 45 study days over all with 30 days of pre intervention and 15 days of the actual intervention using Sense-IT, which is quite a substantial amount of time to receive a good overview about the efficacy and limitations of the technology. It should further be assessed positive that the findings of this study are based on own estimations of the participants in combination with observations of the caretakers, who captured their impressions regarding the aggressiveness of participants within the SDAS-9. This form of multimodal assessment provides a comprehensive overall picture.

The present study should also be considered within the context of a few methodological limitations. Due to the specificity of the population within this study, the sample size happened to be rather small and can be considered a limitation of this study. In fact, the proof-of-concept character of this study, did not necessarily require a huge sample size, but a higher number of participants could have a substantiating effect on the findings. Especially the quantitative research methods of this study could gain importance when the sample size is bigger. Additional research is therefore necessary, before Sense-IT can be confidently applied in clinical contexts. Another limitation regarding the participants is that

the group might have been too specific. Frädrieh & Pfäfflin (2000) found out that 50% of the population in forensic inpatient care, suffers from a personality disorder. Most prevalent in this evaluation was the antisocial personality disorder. It occurred that the current sample exhibits a series of comorbid disorders, that could have functioned as disruptive factors. To determine the efficacy of Sense-IT within autistic people and patients with ID it may be of interest for future research to test patients beyond a forensic setting and with less comorbid disorders. In addition, the conduction of the interviews is also something that could be further discussed. It sometimes remained unclear what participants wanted to explain. A more in depth posing of some questions could have provided a more detailed and comprehensive outcome.

Conclusion

The study could not provide explorative evidence on the relation between ambulatory biofeedback and a decrease of aggression. Nonetheless, it became clear that participants enjoyed using a bio-cueing technology and that usability of Sense-IT can be assessed positive. Some refinements of the technology should be considered, especially with regard to the accuracy with which Sense-IT measures heart rate. For future research it is further recommended to focus on a different target group and extend and revise the baseline procedure.

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Appendix A: Interview Schema

Semigestructureerd interview over uw ervaring met Sense-IT!

Meetmoment: Direct na de onderzoeksperiode met Sense-IT

De afgelopen twee weken heeft u Sense-IT! gebruikt. We willen u nu een aantal vragen stellen over uw ervaring met Sense-IT!. Aan het einde van dit interview hebben we twee vragenlijsten over hoe u de gebruiksvriendelijkheid van Sense-IT! hebt ervaren en over uw tevredenheid met Sense-IT!.

- Hoe heeft u Sense-IT! ervaren / wat vond u van Sense-IT!?
- In welke situaties hielp Sense-IT!?
- In welke situaties hielp Sense-IT! juist niet?
- Kunt u situaties verzinnen (die nu niet plaatsvonden) waarin u Sense-IT! graag zou willen dragen?

- Kunt u situaties verzinnen (die nu niet plaatsvonden) waarin u Sense-IT! juist niet zou willen dragen?
- Welke gedachten (positief/negatief) had u toen Sense-IT! naar uw mening overeenkwam met uw gevoelens?
- Welke gedachten (positief/negatief) had u toen Sense-IT! naar uw mening niet overeenkwam met uw gevoelens?
- Zou u Sense-IT! aan andere mensen aanraden? Waarom?
- Wat vindt u van de trilfunctie van het horloge?
- Wat vindt u van de bolletjes? En wat vindt u ervan dat de bolletjes zichtbaar zijn voor anderen?
- Wat vindt u van het uiterlijk van het horloge?
- Heeft u nog andere opmerkingen?

Appendix B: Client Satisfaction Questionnaire

| CSQ-8 | | | | | |
|-------|------------------------------------------------------------------------------------------------------|------------------------------------|------------------------------------------|-----------------------------------------------|----------------------------------------------|
| 1 | Wat vindt u van Sense-IT!? | Uitstekend | Goed | Redelijk | Slecht |
| 2 | Heeft u het soort inzicht ontvangen dat u hoopte te krijgen? | Nee, beslist niet | Nee, nauwelijks | Ja, in het algemeen wel | Ja, zeker |
| 3 | In hoeverre heeft Sense-IT! aan uw wensen voldaan? | Aan al mijn wensen is voldaan | Aan de meeste van mijn wensen is voldaan | Aan slechts enkele van mijn wensen is voldaan | Aan geen van mijn wensen is voldaan |
| 4 | Stel dat één van uw vrienden of kennissen dezelfde hulp nodig heeft, zou u Sense-IT! dan aanbevelen? | Nee, beslist niet | Nee, nauwelijks | Ja, in het algemeen wel | Ja, zeker |
| 5 | Hoe tevreden bent u over de hoeveelheid informatie die Sense-IT! heeft gegeven? | Zeerv tevreden | Tamelijk tevreden | Tamelijk ontevreden | Zeerv ontevreden |
| 6 | Heeft Sense-IT! u geholpen om beter om te gaan met uw klachten? | Ja, het heeft aanzienlijk geholpen | Ja, het heeft wel wat geholpen | Nee, het heeft eigenlijk niet geholpen | Nee, het heeft de zaak alleen maar verergerd |
| 7 | Hoe tevreden bent u over het geheel genomen met Sense-IT!? | Zeerv tevreden | Tamelijk tevreden | Tamelijk ontevreden | Zeerv ontevreden |
| 8 | Zou u Sense-IT! in de toekomst willen gebruiken? | Beslist niet | Nee, ik denk van niet | Ja, ik denk van wel | Ja, zeker |

Appendix C: System Usability Scale

| SUS | | Helemaal mee oneens | | | Helemaal mee eens | |
|-----|------------------------------------------------------------------------------------------|------------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| 1 | Ik zou Sense-IT! met regelmaat willen gebruiken | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 2 | Ik vind Sense-IT! onnodig ingewikkeld | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 3 | Ik vind Sense-IT! gemakkelijk om te gebruiken | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 4 | Ik heb de hulp van een technisch persoon nodig om Sense-IT! te kunnen gebruiken | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 5 | Ik vind dat de verschillende functies van Sense-IT! goed geïntegreerd waren | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 6 | Ik vind Sense-IT! niet consistent | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 7 | Ik denk dat mensen gemakkelijk kunnen leren hoe ze Sense-IT! kunnen gebruiken | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 8 | Ik vindt Sense-IT! erg moeizaam in het gebruik | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| SUS | | Helemaal mee oneens | | | Helemaal mee eens | |
| 9 | Ik voel me erg zelfverzekerd wanneer ik Sense-IT! gebruik | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

| | | | | | | |
|----|------------------------------------------------------------------------------|---|---|---|---|---|
| 10 | Ik heb een boel dingen moeten leren voordat ik aan de slag kon met Sense-IT! | o | o | o | o | o |
|----|------------------------------------------------------------------------------|---|---|---|---|---|