Wearables for residents of nursing homes with dementia and challenging behaviour: Values, attitudes, and needs

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Abstract

Background: Challenging Behaviour (CB) occurs in up to 80% of nursing home residents with dementia. Identifying stressors causing CB is difficult (as residents themselves cannot indicate what is experienced as stressful), thereby hampering the psychosocial approach. Nowadays, stress-related biomedical variables, such as (aberrant) physical activity, skin temperature, heart activity, and skin conductance, can be measured continuously and relatively easily using wearable sensors. Next to validation of algorithms (i.e. the relationship between wearable data and CB), it is of utmost importance to consider the different values, attitudes, and needs of all stakeholders involved to successfully develop, apply and implement this technology.
Objective: To identify the values, needs, and attitudes of multiple stakeholders regarding wearables in the care of people with dementia and CB.
Method: A qualitative study was conducted, in which a real-life context was created in a Dutch nursing home. Two residents with CB wore the Empatica E4 wristband for three half-days. Multiple stakeholders (i.e., eight involved nurses and eight informal caregivers) were interviewed. Subsequently, results were used for designing two focus groups. The first focus group included formal (n=6) and informal (n=6) caregivers. The second focus group consisted of community-dwelling people with dementia (n=7) and their informal caregivers (n=5) and case managers (n=2).
Results: Stakeholders accepted the wearable as a supportive technology in the care of people with dementia and CB. Expected value, user comfort, need for information, and design (including customizability and stigmatization) were important themes. During the focus groups, explicit recommendations were given by the participants with respect to the wearables' design.
Conclusion: In order to enhance the adoption of wearable sensors in CB and dementia on an individual level, information about the technology and the design of the wearable deserves more explicit attention in clinical practice and future research.

Keywords: Challenging behaviour, dementia, wearables, biomedical variables, technology adoption

INTRODUCTION

In people living with dementia, challenging behaviour (CB; also referred to as Behavioural and Psychological Symptoms of Dementia (BPSD), distressed behaviour or neuropsychiatric symptoms), such as anxiety, agitation, depression, disinhibition, and a variety of behaviours perceived as problematic, pose a major problem. CB occurs in up to 80% of residents with dementia, and is the primary reason for institutionalization of persons living with dementia in a nursing home (Zuidema, Derksen, Verhey, & Koopmans, 2007). Health care costs are positively correlated to the degree of CB, independent of confounders such as cognitive impairment and comorbid conditions

(Murman et al., 2002). Furthermore, CB has a major impact on quality of life of residents, as well as on fellow residents, family and both formal and informal caregivers (Hazelhof, Schoonhoven, van Gaal, Koopmans, & Gerritsen, 2016; Kales, Gitlin, & Lyketsos, 2015; Mukherjee et al., 2017; Schmidt, Dichter, Palm, & Hasselhorn, 2012). In health care professionals this results, among others, in high perceived stress levels and burnout (Costello, Walsh, Cooper, & Livingston, 2019).

In clinical practice, psychotropic medication plays a major role in the treatment of CB (Selbæk, Kirkevold, & Engedal, 2008). However, this course of treatment induces serious side effects

(especially in older people with comorbidities) and often it is not sufficiently effective (Andrade & Radhakrishnan, 2009; Kales et al., 2015; van Iersel, Zuidema, Koopmans, Verhey, & Olde Rikkert, 2005). A psychosocial approach (i.e., non-pharmacological) to treat CB is considered the first-choice course of therapy (Kales et al., 2015; Tible, Riese, Savaskan, & von Gunten, 2017). Crucial elements in this approach (which can, for example, be found in the BSPD-DATE method, see (Tible et al., 2017)) are 'Describe and measure', 'Analyse', 'Treat' and 'Evaluate'. Examples of 'describe and measure' are: which behaviour is shown and when does this behaviour occur exactly? Is there emotional dysregulation? Which triggers can be observed? Examples of questions raised in 'analyse' are: can the CB be explained? Are there comorbidities? 'Treat' applies to, amongst others, work on modifiable factors and the application of non-pharmacological interventions. Finally, 'evaluate' entails aspects such as feasibility and effectiveness of the approach.

Although the causes of CB are multifactorial, personal, and contextual (Kales et al., 2015; Tible et al., 2017), stress is often mentioned as a key factor. The Progressively Lowered Stress Threshold (PLST) model (Smith, Gerdner, Hall, & Buckwalter, 2004) explains the relationship between stress and CB as a consequence of reduced (cognitive and functional) ability to deal with environmental demands in people with dementia. Simultaneously, the stress level these people can manage decreases. When the experienced stimuli exceed the individual's stress threshold, CB can occur. Furthermore, in people with dementia the ability to communicate and express needs or feelings is often impaired over time (Banovic, Zunic, & Sinanovic, 2018). This affects the ability of formal and informal caregivers to identify stressors causing CB and, consequently, the psychosocial approach to treat CB.

Insight into the emotional states (including stress) of a person, is of utmost importance when assessing and managing CB (Kales et al., 2015; Tible et al., 2017). This insight can be obtained in several (complementary) ways, for example by analysing one's facial expression, voice, gestures, and body posture (Grabowski et al., 2019). Additionally, as it is well-known that the autonomic nervous system reacts to stress, real-time measurement of biomedical variables, such as skin temperature, heart rate variability, blood volume pulse, and skin conductance by means of wearable can provide insight into a person's emotional state (Grabowski et al., 2019). For example, it has been shown that, by using different kinds of sensors, agitation and aggression could be detected in people with dementia (Khan, Ye, Taati, & Mihailidis, 2018). This might lead to a more

optimized living environment, personalized interventions, and/or prevention of CB, which ultimately contribute to the quality of life of people living with dementia, including their formal and informal caregivers.

When choosing technologies to assist in obtaining insight into the emotional state of a person, several issues need to be considered. The technology's measurements and algorithms used to process the data need to be validated. When used in Europe, technologies should have a legal Conformité Européenne (CE) mark (Symbol placed on the product by the manufacturer, certifying that it complies with the requirements of the applicable directives of the European Union (European Commission, 1993).). Furthermore, the General Data Protection Regulation (GDPR. See https://gdpr-info.eu/. The GDPR is legislation that describes the conditions for the collection of personal data (including patient and research data, see (McCall, 2018)) and how they should be processed.), which is enforced since May 2019 in the European Union, needs to be considered. Informed consent regarding collection and processing of personal data, including purpose limitation (i.e., specified, explicit, and legitimate purposes), data minimisation (i.e., limited to what is necessary), storage constraints (i.e., no longer than necessary), accuracy, right to access, and the right to be forgotten (ie., right to erase) are some key principles of the GDPR. Furthermore, in persons showing CB, it is important that the technology is minimally intrusive, i.e. places no constraints on activities and does not require active compliance. All in all, selecting suitable technologies to assist in obtaining insight into the emotional state of a person with CB, is a complex undertaking for clinicians and researchers.

At the moment, various wearable sensors are commercially available to measure biomedical variables (for recent overviews see (Peake, Kerr, & Sullivan, 2018; Saganowski et al., 2020)). However, the applicability, in terms of user acceptance and implementation in the care setting, of such wearables in the context of CB and dementia is currently not known. When applying and implementing new technology, such as wearables, in health care, it is of utmost importance to consider the different values, attitudes, and needs of all stakeholders involved. Many promising technologies are not adopted in health care (Greenhalgh et al., 2017). One of the major obstacles is the lack of acceptance of stakeholders, such as the client, but also (in)formal caregivers (Brewster, Mountain, Wessels, Kelly, & Hawley, 2014; van der Zijpp, Wouters, & Sturm, 2018). Previous studies indicate that wearables could be used in the care of people with CB and dementia (Kikhia et al., 2015; Melander, Kikhia, Olsson, Walivaara,

Figure 1. The Empatica E4 wristband.

& Savenstedt, 2018; Melander, Martinsson, & Gustafsson, 2017), as the wearable's output has shown to be correlated with (types of) CB and assistant nurses perceive the objective data as support of their observations. Further research is needed as it is currently unknown how the informal caregivers or (proxies of the) people with dementia perceive this supportive technology to facilitate a psychosocial approach to prevent or reduce CB. Moreover, it is unknown what the needs and attitudes of the stakeholders are regarding the design and use of this sensor technology. These insights can be used in refining the design of wearables in health care, to increase the actual adoption of this technology in health care.

MATERIALS AND METHODS
Two studies were conducted: in the first study, a real-life situation was created in which two persons with CB and dementia in a Dutch nursing home wore a wearable. Involved stakeholders were interviewed regarding their values, needs, and attitudes. In the second study, focus groups with (in)formal caregivers and community-dwelling people with dementia were created in order to identify needs regarding the hardware design of a wearable.

Real-life situation and interviews
Participants
Researchers recruited participants by sending an e-mail to the nursing staff and displaying a recruitment poster in the nursing home. Interested participants could contact the researcher directly. Eight informal caregivers (two of them legally representing the two included residents, five of them related to other residents of the participating nursing home, and one of them not related), and 8 nurses of the nursing home were interviewed. In order to identify their values, needs, and attitudes regarding the wearable sensor, a real-life experience was obtained before the interview. To this end, the nursing staff selected two female residents of a Dutch nursing home (78 and 86 years old, referred to as residents A and B, respectively) as being residents with CB, eligible for wearing the sensor.

Method
In order to create a real-life situation for the in-depth interviews, two selected female residents wore the Empatica E4 (*Figure 1*) three to four hours a day for three days, leading to a total of six observation sessions. The Empatica E4 is a medical grade wearable device with a CE mark, worn on the wrist, which provides access to all raw signals that are technologically validated (van Lier et al., 2020). All the sensors are combined in one device. Peripheral skin temperature and electrodermal activity are sampled at rates of 4 Hz. Movements are measured by a 3-axis accelerometer with a sampling rate of 32 Hz. Finally, heart rate and blood pulse volume (BPV) are measured by using photoplethysmography (PPG) at a sampling rate of 64 Hz. It can be used offline (downloading the data after recording) or online (streaming the data via Bluetooth to a device such as a smartphone during the recording) mode. In both offline and online recording, data are streamed to the Empatica server where they are stored. When using the Empatica, a user automatically 'opts in' for the storage of data on Empatica's server. Once the data is stored, a user can opt-out by sending Empatica an e-mail, requesting to delete the personal data (conform to the GDPRs' *"right to be forgotten"*). To simulate a real-life situation as closely as possible, the Empatica was turned on (and all data was recorded). As the quantitative measurements themselves were not part of this study, this data was not analysed.

A nurse put on and took off the wearable. To ensure data collection, the offline recording was chosen. This way, the resident was not restricted in her movements and space (i.e., she could move around freely). After each observation, the researcher connected the Empatica to a computer, and the (de-identified) measurements were downloaded of Empatica's server in Microsoft Excel files. These measurements include skin temperature, skin conductance, movement, heart rate, and blood volume pulse (BVP).

Nurses and informal caregivers were interviewed regarding their opinions about the use of this technology. Before conducting the interview, the potential value of using a wearable was explained to the (in)formal caregiver. It was explained that monitoring stress-related parameters by using a wearable could potentially help in caring for people with CB in the future, but that it is currently unknown if and to what extent CB can be prevented or reduced by using wearables in the daily practice of a nursing home. They were asked about whether they would use the wearable on future occasions, and their potential worries regarding the use of this technology. Interviews were conducted individually, lasted approximately 30-45 minutes, and were recorded by using a voice
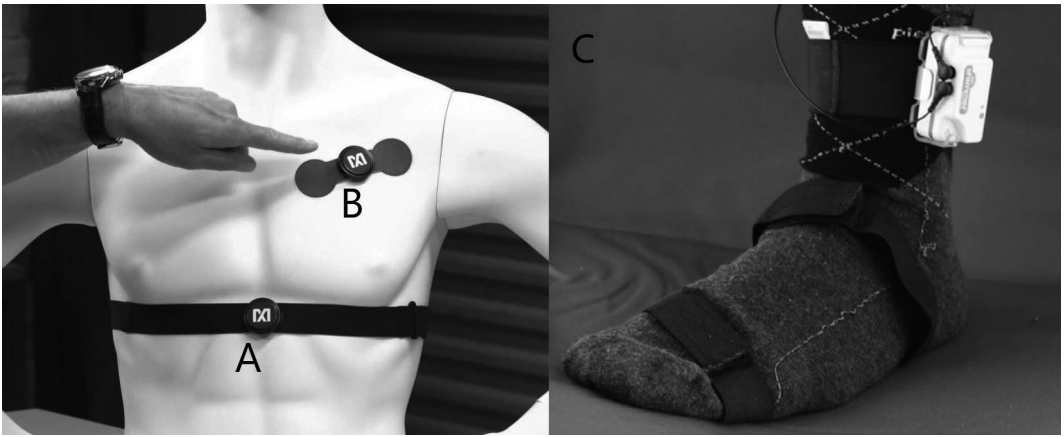
Figure 2. Wearable sensors were shown to participants of the focus groups. A chest belt (A), patch (B) (reprinted from "MAX-ECGMONITOR," by Maxim integrated, 2021. (https://www.maximintegrated. com/en/products/interface/sensor-interface/MAX-ECGMONITOR.html). In the public domain) and sensor sock (C; Reprinted from "The effects of a bioresponse system on the joint attention behaviour of adults with visual and severe or profound intellectual disabilities and their affective mutuality with their caregivers" by K. Frederiks, P. Sterkenburg, E. Barakova, & L. Feijs. 2019. Journal of Applied Research in Intellectual Disabilities, 32(4), p4. Copyright 2019 by John Wiley & Sons, Inc. Reprinted with permission.

recorder. See supplementary materials for the interview guide of these semi-structured interviews.

Analysis

Interviews of nurses and informal caregivers were transcribed verbatim. Personal names were not transcribed (i.e. a code was used), and after transcription, the audio recording was deleted. A summary of each transcript was sent to the participant, so the researcher's interpretation could be checked (member check). Subsequently, transcripts were analysed according to the principles of qualitative content research (Moser & Korstjens, 2018). An iterative process was used, in which data collection (i.e., interviewing) and analysis (coding) are performed in parallel. Insights from the one interview are taken into account for the next interview until saturation occurs (i.e., no new insights are gathered). Textual fragments were extracted (initial coding) and categorized. Based upon these categories, themes were formulated. During the whole process, at least two researchers were involved to ensure the trustworthiness of the transcript's interpretation (peer-review principle).

Focus groups

Participants

Participants of focus groups did not participate in the previous interview study. The first focus group was held at a different but similar department of the same Dutch nursing home as study 1. The researcher recruited participants by sending the nursing staff and the clients' legal representatives an e-mail. The research population consisted of 6 formal (1 family coach, 1 psychologist, 2 nurses, 1 member of the client council, and 1

medical specialist geriatric medicine) and 6 informal caregivers of residents. The second focus group was held at a regular focus group meeting of the platform 'Innovate Dementia 2.0' (van den Kieboom, Bongers, Mark, & Snaphaan, 2019) and consisted of community-dwelling people with dementia (n=7), their informal caregivers (n=5) and 2 case managers.

Method

During both focus groups, one researcher acted as moderator, asking open-ended and follow-up questions. Another researcher acted as observer, making notes of non-verbal communication.

The first focus group lasted 2.5 hours. During this focus group, the Empatica E4 (*Figure 1*) was used to measure stress-related parameters in a volunteering participant, who was subjected to the city scrappers heights virtual reality game 'Richies Plank Experience' (Link: https://store.steampowered.com/app/517160/Richies_Plank_Experience/) (using a standalone Oculus Quest VR headset). This game, developed by the Toast from Steam platform, is known to affect psychological and physiological responses (Ramdhani, Akpewila, Faizah, & Resibisma, 2019). This experience was used to show the members of the focus group how stress-related parameters using the Empatica E4 can be measured and visualised, and to start the discussion. Subsequently, the focus group discussed which design properties a wearable should have in order to be adopted in clinical practice. Next to the Empatica E4, three currently available methods of measuring stress-related parameters were shown as examples to the participants: A

Table 1. Identified themes during the interviews and focus groups, with respect to the use of wearable sensors in the care of people with dementia and challenging behaviours.

Theme	Recommendations
Expected value	• An explicit goal for the individual wearer should be present • The benefits should outweigh the costs of invested time • The benefits should outweigh the inconvenience of the wearer • Practical consequences of the wearable's measurements should be clear (such as follow-up actions for caregivers after the wearable signals stress in a person with dementia)
Need for information	• No concerns were identified regarding privacy (as a result of clear communication upfront and a high level of trust in the nursing home) • There should be specific and clear instructions regarding using the wearable
User comfort of the wearable	Should be • comfortable • easy to use • water resistant • integrated with other sensors/functions • non-intrusive (e.g., be placed out of sight, no blinking lights)
Customizability	Should • have aesthetic value for a person • be adjusted to practical properties and characteristics of the wearer (e.g. a sensor sock is not suitable for wearers who take their socks of regularly).
Stigmatization	• Wearing the wearable should not be associated with 'showing you have problems'.

chest band and patch (*Figure 2A* and *B*, able to measure ECG (Maxim Intergrated, 2021)) and a sensor sock (*Figure 2C*, able to measure skin conductance (Frederiks, Sterkenburg, Barakova, & Feijs, 2019)). See supplementary materials for a detailed outline of the focus group.

The second focus group lasted one hour. During this focus group, multiple wearable sensors were shown (*Figures 1* to *2*), explained, and discussed. See supplementary materials for a detailed outline of the focus group.

Analysis
Focus groups were transcribed verbatim. Subsequently, transcripts were analysed according to the principles of qualitative content analysis (Moser & Korstjens, 2018). Textual fragments were extracted (initial coding) and categorized. Based upon these categories, themes were formulated. During the whole process, at least two researchers were involved to ensure the trustworthiness of the transcript's interpretation (peer-review).

Ethical aspects
The local board of research and ethics (Fontys Commissie Ethiek van Onderzoek reviewed this study with the following reference *"Wouters-Graaf260520 FCEO"*). All data were de-identified by the researchers and processed confidentially. All participants (in the case of the two residents the legal representatives) in this study gave their informed consent, after receiving verbal and written information. The two residents were, due to dementia, not able to provide their informed consent. Therefore, a formal caregiver who knew the resident well (i.e., was involved in the resident's daily care) carried out the 'putting on' and 'taking off' of the wearable. This experienced caregiver was able to interpret the residents' behaviour and able to estimate whether the resident showed behaviour that should be interpreted as resistance or discomfort indicative of not giving consent. Both residents in our study did not show signs which could be interpreted as 'not giving consent'.

RESULTS
Observations of residents and wearable data
The wearable was able to successfully measure stress-related parameters in both residents with virtually no missing values without a known cause. During one session, one of the residents switched off the wearables herself. Since the offline recording mode was chosen (see introduction), this was not immediately noticed, leading to 20 minutes of missing data. As the wearable has to be tightened around the wrist, one of the two residents showed a brief moment of discomfort while the wearable was put on. Once the wearable was on the wrist, no signs of discomfort related to the wearable were observed. Also, during the taking off of the wearable, no signs of discomfort were shown.

Informal carers and nursing staff (interviews)
Generally, informal caregivers and nurses accepted the use of the wearable as a supportive technology in the care of people with CB and dementia. The explicit intention and benefits of the use, user comfort, privacy and data handling, understanding the technology and design were important considerations. In total four themes emerged: 'Expected value,' 'need for information' and two more hardware-related themes 'user comfort,' and 'sensor design'. See *Table 1* for a summary of all identified themes.

Expected value
Both the informal caregivers and nursing staff did not consider the wearable as an 'all-round technology to be used on anyone'. Rather, the use of the wearable should have explicit goals for a specific resident. The nursing staff indicated that they did not want to spend valuable care-time if the foreseen benefit of the wearable for the specific

resident was not evident to them. Likewise, also informal caregivers found it important to know the potential individual benefits, before deciding whether to bother the resident with the wearable, as they anticipated some level of resistance to wearing the wristband by the residents.

Nurse: *"…Naturally, that takes a lot more time [to use this technology]. And that is a pity regarding the care of people, because I'm like old-fashion hands-on-bed ['hands-on-bed' is a Dutch expression, meaning that the caregiver's actions should be aimed at practical patient care.]. And not on the computer. But if we profit in the sense that we can decrease the medicine use than I think it's fine. Then I'll go for it."*

Informal caregiver (husband of a resident): *"Yes if it is necessary and useful, I'm a proponent to use it in dementia. But to wear something just like that… no."*

Need for information
Both informal caregivers and the nursing staff were not concerned about privacy issues regarding the wearable, as they consider biomedical variables as de-individualized values. The participants trusted the researchers and nursing home regarding good data handling, as they felt well-informed.

Nurse: *"What it measures, is heart rate and temperature and those things you [referring to the interviewer] mentioned earlier … yes these will be measured and saved, of course. But in principle, you can process these things anonymously, without a name. Then there is still a lot of privacy. Little violation of privacy."*

Informal caregiver (daughter of a resident): *"…look, you ask us for permission and providing us with letters. I assume that you know that you have to process the data confidentially, or at least handle the personal data confidentially…"*

To be able to accept and/or work with the wearable, stakeholders indicated they want to receive written information about the technology and are willing to follow a workshop.

Nurse: *"… I would like information about how we can use it. So that it is used properly."*
User comfort
Additionally, in order not to spend more time than necessary, they also indicated that they want the technology to be reliable (i.e., no malfunction) and easy to use. If residents would show discomfort related to the wearable, the wearable would not be used. The degree of discomfort experienced differs between residents according to the nurses.

Nurse: *"… Yes if the resident is not bothered by it then I think it is fine to use. As soon as they are bothered or hindered by it, it would be a different story I think."*

Nurse: *"…just like Mrs. A, I think it doesn't bother her at all. I don't feel that it is annoying […] putting it on was challenging […] taking it off was very easy. I think e.g. Mrs. A was fiddling with it […] that really differs per resident, I think."*

Sensor design
Stakeholder thought the size of the Empatica E4 was too big, worrying them that it might draw too much attention (and accompanied resistance). The design of the wearable was indicated as being not appropriate for people with dementia. The wristband is worn like a watch, but not recognizable as a 'classic watch'. It has to be tightened around the wrist, which is uncomfortable for people with vulnerable skin. Finally, the power button is on the outside of the watch, within reach of the person wearing it. For the nursing staff, it was not always clear whether the wearable was measuring properly. It was suggested that the wearable could be personalized (e.g., in the resident's favourite colour, or favourite type of jewellery).

Informal caregiver: *"Well, I hope that they do not delete all the data that is on the device…. [laughs] Nothing is more fun than fiddling with the buttons."*
Nurse: *"Tightening the wearable she [referring to the resident] found uncomfortable. She showed that, because I think she said 'ouch' or something like that, when I had to push. So that was clear. It was not comfortable, because it has to be pretty tight."*

Informal carers, nursing staff, and community-dwelling people with dementia (focus groups)
As the hardware design was an important theme during the interviews, the two focus groups discussed this aspect of wearable sensors in depth. Generally, informal caregivers, nurses, and community-dwelling people with dementia accepted the use of wearable sensors as a supportive technology in the care of people with dementia, as long as the foreseen benefits are evident (expected value). Regarding the sensor design, three themes emerged: 'user comfort,' 'customizability' and 'stigmatization'. See *Table 1* for a summary of identified themes.

Expected value
Participants explicitly indicated that it was important to consider the practical consequence of measurement (i.e., required follow-up action). Furthermore, measurements of a wearable sensor were considered to be useful for (in)formal

caregivers, but not so much for people with dementia themselves.

Participant: *"well I know when I'm stressed. I don't really need this for that"*

Participant: "I would like to distinguish between the momentary reaction to a thing, so see 'oh what should I do then', and for later analysis that it is recorded somewhere, and what has that behavior been like and what do you do. The latter seems to me meaningful…. Very useful. But not for the patient himself, but for people who analyze."

One participant was concerned regarding possible false positives: *"…And what about false alarms, if you walk outside on a hot day, it will also indicate [referring to stress detection based upon skin conduction], but then nothing is wrong."*

User comfort
Participants empathized that a wearable sensor should fit comfortably and should not be experienced as an additional stimulus. Ideally, a sensor should be placed out of sight or, when this is not possible, have another function such as a classic watch. Furthermore, water resistance and small sizes where indicated as valuable properties. The Empatica E4 was experienced as too big, too tight, not recognizable and therefore uncomfortable. Participants worried that wearing this device would actually trigger stress in people with dementia. It was suggested that a dummy-wearable could be worn by the person with dementia, so the person was used to the wearable during the actual measurements.

Participant: *"Perhaps people can wear a non-working wearable beforehand to get used to it. Because otherwise you already have stress from that wearable alone and that is not the intention."*

Participant: *"If the wristband [referring to the Empatica E4] has to be as tight as I am wearing it now, I can imagine that it induces stress. It irritates!"*

Customizability
No participant could think of a design of a wearable sensor that would be suitable for all people with dementia. Small and flat wearable sensors in clothing were mentioned as a good option for people who do not take of their clothing during the day. As a general design, a patch (like a band aid, see *Figure 2B*) was estimated as most promising. In their opinion, however, a wearable should be modifiable for a person (like jewellery), or a person should be able to choose between different wearables.

Participant: *"… But we [referring to a nursing home] also had a band-aid because some of them*

[referring to residents with dementia] have those fentanyl patches too. We stick it on the back, they won't get it off, but some will get it off anyway. So, yes, it really differs from person to person."

Stigmatization
Participants were worried about stigmatization. For example, they found that the sensor sock (*Figure 2C*) was too stigmatizing, especially if the sensor would be partly insight.

Participant: *"… It [referring to the sensor sock] looks like a house arrest ankle bracelet…" Other participant replies "…I would not dare to wear this in a supermarket. I think that a big part of the community would think I am under house arrest"*

Discussion
The current study shows that multiple stakeholders generally accept the use of the wearable as an assistive technology in the care of people with CB and dementia in a Dutch nursing home. Expected value, user comfort, provided information and the hardware design (including customizability and stigmatization) were important themes when identifying needs, attitudes, and values. This is in line with earlier studies, which show that nursing staff experiences this type of technology (i.e., sensors measuring stress-related biomedical variables) as helpful, contributing to more insight into the residents' needs (Kikhia et al., 2015; Melander et al., 2018). In the current study, however, signs of compliance issues were observed, as at one out of six sessions one client showed a brief moment of discomfort while putting on the wearable, and switched off the wearable during the observation. Additionally, the design of the wearable used in the real-life context (Empatica E4, *Figure 1*), was experienced as suboptimal by nurses and legal representatives of the residents. Therefore, to successfully implement this technology in clinical practice, a wearable should be designed that is experienced as appropriate for people with dementia by multiple stakeholders. To this end, a more customizable wearable sensor system should be developed, considering the perspectives of multiple stakeholders (e.g., using a user-centered design approach). This would be an important step for successful implementation of the use of stress-related biomedical variables in the care of people with CB.

All stakeholders (i.e., nurses, informal caregivers, and people with dementia) indicated that for them the foreseen benefits of using this technology for the individual wearer are of utmost importance, along with user comfort. It is known that perceived usefulness and ease of use have a major impact on technology acceptance in general, as described by the Unified Theory of Acceptance and Use of Technology (UTAUT (Venkatesh,
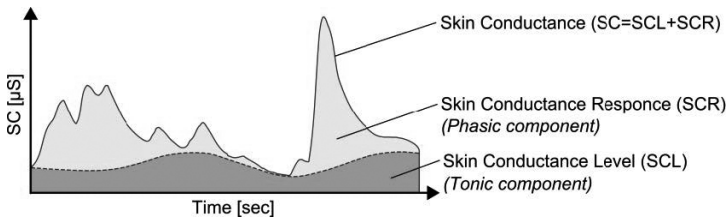
Figure 3. The tonic and the phasic component of skin conductance. Reprinted from "An investigation of vehicle interface operation comfort" by G.V. Georgiev, Y. Nagai, S. Noda, D.W. Junaidy & T. Taura. 2013. Proceedings of the 19th International Conference on Engineering Design (ICED13), 7, p3. CC-BY-NC.

Morris, Davis, & Davis, 2003)). This importance of perceived usefulness has also been shown in dementia care specifically (de Veer, Fleuren, Bekkema, & Francke, 2011; Kramer et al., 2015), as is the ease of use. Nurses also indicated the importance of their involvement in the introduction of the technology and to understand how the use of a wearable interferes with their nursing practice, as well as the need for information on technical aspects. This is in line with the constructs 'coherence' (making sense of and attributing value to a new manner of working), 'cognitive participation' (which involves understanding changes in work processes and openness to the (new) practice, and 'collective action' (which is about actual confidence in being capable of doing it together with colleagues) of Normalisation Process Theory (NPT), which explains what it takes to normalise innovations into usual care (May et al., 2018). Finally, regarding the hardware design, stakeholders indicate that a wearable sensor should be customized to the personal preferences of the wearer (practically, but also aesthetically), and should not be experienced as stigmatizing. Aesthetic and stigmatizing factors were also identified as important factors during adoption of assistive health care tools in other studies (e.g. (Bailey et al., 2019; Renda, Jackson, Kuys, & Whitfield, 2016).

During the real-life situation of this study, we choose to use the 'offline recording mode' of the Empatica E4. This mode is of limited use in real-life scenarios. Only an online mode would allow for instant feedback about the stress-related parameters, indicating whether a resident might be stressed. Caregivers could consequently (re) act appropriately. However, we did not find a wearable sensor that had an interface allowing near real-time usage of its signals and that is available for clinical practice - i.e., commercially available and having the legally obligatory (medical) certification to use in a Dutch Nursing home - and suitable for people with CB (i.e., not intrusive). For example, the Empatica E4 (commercially available, has the necessary certification, and is minimally intrusive) has an online

mode (via Bluetooth) with a user interface (Android or iOS) displaying stress-related parameters. However, their current software does not have an algorithm that allows for instant visualizations and conclusions regarding stress. The stress-related parameters, such as skin conductance and heart rate, are displayed as absolute values. However, it does not distinguish between tonic or phasic skin conductance, and it does not show heart rate variability (HRV), all crucial parameters (which often even need to be combined) when drawing valid conclusions about the stress level (Lai Kwan et al., 2019; Nath, Thapliyal, Caban-Holt, & Mohanty, 2020). Regarding skin conductance, it is important to differentiate between the total signal (often called skin conductance) and different components of this signal: tonic and phasic (*Figure 3*). The tonic component (often called the Skin Conductance Level) represents a slowly changing baseline level of skin conductance. The phasic component (often called the Skin Conductance Response) is superimposed on the tonic component, is rapidly changing, and reflects a response or reaction (e.g. in reaction to environmental events). Changes in these components of skin conductance are well accepted as changes in stress level (Boucsein, 2012). Currently, these parameters (HRV and the tonic and phasic component of skin conductance) need to be inferred offline, with additional analyses.

Another important limitation is that when the Bluetooth connection is lost, the Empatica is switched off completely (i.e., it will not switch automatically to offline recording mode). For the residents with CB, the online recording mode is too intrusive, as this means that their movement is restricted, a caregiver with the Bluetooth connection has to follow them around, or they have to wear a phone on themselves (which is not possible in the vast majority of the clients with CB). In conclusion, the wearable sensors that are available for (Dutch) clinical practices are currently not allowing a mode for real-time stress detection feasibly. Therefore, next to making the wearable's hardware design suitable for people with dementia, developers should also aim for technology and software interfaces allowing for real-time stress detection feasible in care facilities. The design of this user interface (UI) should be considering the perspectives of multiple stakeholders (e.g., using the user-centered design) to enhance the adoption of this technology.

The application's interface design fell outside the scope of this study. However, the user experience (UX) of the external UI is a major factor in the adoption of this technology of (in)formal caregivers. Participants who were interviewed based their responses upon the assumption that a wearable was able to monitor stress-related parameters, which could potentially help in caring for people with CB in the future. Participants were told that it is currently unknown to what extent and under which exact circumstances CB can be prevented or reduced by using wearables in the daily practice of a nursing home. As the UI design has a major impact on the usefulness and ease of use of a wearable (and thereby on the adoption of the wearable in daily practice by care professionals (Venkatesh et al., 2003)), an iterative design and evaluation process for the UI of the app connected to the wearable (using a user-centered design (van der Zijpp et al., 2018)) will be a major factor in the adoption of this technology. The current study focused on the body-attached hardware device (which can be considered to be the first part of the technological system), and participants did not experience the UI design of the Empatica E4 (which can be considered to be the second part of the system). As participants did not evaluate the wearable's output, they were therefore unable to reflect on this aspect. UI development and evaluation targeted at the specific roles and stakeholders would be an important next step in creating a wearable assistive technology which is adopted in caring for people with CB.

During the real-life situation of the study, we used the Empatica E4. Virtually no data loss (defined as no registered measurement during one minute) was observed when the Empatica E4 wristband was measuring for a longer period of time. In a recent study (van Lier et al., 2020), van Lier and colleagues studied the quality and validity of the skin conductance and heart rate measurements of the Empatica E4. It was concluded that this device is valid when studying strong sustained stressors in healthy young adults (van Lier et al., 2020). For short-lived stressors (such as startle responses), the Empatica E4 might be less suitable. Currently, it is unknown if the Empatica E4 wristband could validly detect stressors playing a role in CB in a valid manner. Future studies should evaluate the relationship between the measurements of wearable sensors such as Empatica E4, (distressed) behaviour, and stressors to determine its usability in clinical practice in the care for people with CB. It has been shown that with artificial intelligence (AI) accurate stress-predicting algorithms can be developed, using a combination of stress-related parameters as measured by the Empatica E4 (Gjoreski, Luštrek, Gams, & Gjoreski, 2017; Khan et al., 2018; Sevil et al., 2017). The focus in the field of AI is shifting from *"applied AI"* (i.e., predict) towards *"explainable AI"* (i.e., predict and explain). This promising trend helps to build more fair and unbiased algorithms for society and accelerates the acceptance of AI-enabled solutions (Adadi & Berrada, 2018). Advances in sensor technology and hardware design will also enable edge computing in the near future (e.g. (Jia, Han, Xie, & Du, 2019)). Edge computing refers to a computational paradigm in which data processing is performed close to the data source and on the sensor device itself. This allows for practical privacy-by-design solutions avoiding streaming of raw sensor data to computing devices and/or the cloud. This will further facilitate the acceptance of wearable technology.

CONCLUSIONS

The values, needs, and attitudes of formal and informal caregivers regarding wearable sensors in the care of people with CB in a Dutch nursing home were studied. In-depth interviews showed that the (in)formal caregivers accepted the wearable as a supportive technology in the care of people with CB. However, to enhance the acceptance on an individual level (and thereby the actual adoption of this technology), information about the technology and the design of the wearable deserves more explicit attention in clinical practice and future research. Additionally, next to making the wearable's design suitable for people with dementia, developers should aim for technological solutions and interfaces that allow real-time stress detection in care facilities.

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APPENDIX I: INTERVIEW GUIDE OF THE IN DEPTH INTERVIEWS

The following interview guide was used while conducting the semi-structured interviews. Depending on the participant's answer, questions could be rephrased or specific follow-up questions could be asked. The exact language use was adapted to the participant, in which also the nature of the relationship with the resident was considered.

Start of the interview
• The written information letter (which the participant received earlier) is verbally summarized by the interviewer. The participant is able to ask questions.
• General information is obtained (age, gender, profession, relationship with the resident(s)).
• With consent of the participant, the voice recorder is turned on.
Introductory questions

Questions for both formal and informal caregivers:
 • Which problems do you experience regarding distress behaviour?
    o How do you deal with this?
    o What do you think about the current care regarding this behaviour?
 • What do you think about the fact that a wearable is used?
    o Why do you think this?
    o What do you think the function of the wearable is?
    o How do you feel about the fact that the resident is being observed while using the wearable?

Impact of the wearable

Questions for both formal and informal caregivers:
 • To what extent do you think wearing the wearable influences the daily life of the resident?
    o How would you notice this?
    o (in case of interviewing a participant which experienced working with the wearable: Which changes did you observe?)

Impact of the wearable	

- What do you think are the profits of using a wearable?
    - o   In your opinion, are there also disadvantages? If so, which ones?

Questions for formal caregivers:
- To what extent do you think using the wearable influenced your daily activities at work?
    - o   How did you notice this?
    - o   How do you feel about this (also regarding the future)?

What would you change about the wearable to facilitate your work?

Appearance of the wearable

Questions for both formal and informal caregivers:
- While showing the wearable (Empatica E4): What do you think about the wearable's appearance?
    - o   Why do you think that?
    - o   What do you think about the colour?
    - o   What do you think about the size?
    - o   What do you think about the LED-light (on the front?) for user feedback?
    - o   What would you like to change regarding the appearance?
    - o   Do you think the appearance has an effect on the daily life of the resident?

Using the wearable (only for formal caregivers who experienced working with the wearable)
- How did you experienced putting on the wearable?
- How did you experienced turning on and off of the wearable (i.e. finding and using the power button)?

Data and privacy

Questions for both formal and informal caregivers:
- How do you feel about the fact that the wearable stores and gives insight in personal data, such as heart rate, skin conductance, temperature, etc.
    - o   Why do you think that?
    - o   Do you trust the data the wearable generates?
    - o   Do you know other wearables which you might trust more?

Future

Questions for both formal and informal caregivers:
- In your opinion, what would it mean for your organization/residents if the wearable would be used on a large scale?
    - o   Why do you think that?
    - o   Under which conditions do you think this large-scale use is acceptable?
- Which changes do you think are necessary to improve the wearable?
    - o   Why do you think that?
- Would you recommend this wearable to other residents or nursing homes, once it is established hat challenging behaviour can be reduced by using a wearable?

Questions for formal caregivers:
- What would motivate you to use the wearable during the daily care of residents?
    - o   Under what circumstances would you use the wearable?
    - o   Are there circumstances in which you would not use the wearable?

Closing the interview

Questions for both formal and informal caregivers:
- Thank the participant for participate
- Asking whether the participant could check the summery of the interview (member check)

APPENDIX II: THE FIRST FOCUS GROUP (CONSISTING OF (IN)FORMAL CAREGIVERS OF A NURSING HOME)

The following schedule was used while conducting the first focus group. Depending on the participant's answer, questions could be rephrased or specific follow-up questions could be asked. The exact language use was adapted to the participant, in which also the nature of the relationship with the resident was considered.

Time (minutes)	Activity
0-10	Researchers (n=3) and participants (n=12) introduced themselves. Additionally, each participant elaborated on their profession and their experience with people with dementia.
10-20	Signing of the informed consent forms.
20-40	One volunteer is asked to experience the Virtual Reality environment (i.e. Richies Plank Experience) which induces stress. Simultaneously, stress-related parameters are measured using the Empatica E4. The group was asked to reflect on the stress-related measurement, including their opinion regarding the Empatica E4.
40-60	The group was asked to react on the following questions and statements: • You have now seen the Empatica E4, what do you think is a strength of this design? • And what do you think could be improved here?

40-60	• In which situations would you like to measure stress?
	     ○ Or which parts of the day?
	 • How do you deal with BPSD?
	     ○ Can you give an example of such a situation?
	     ○ Do you know why people are showing BPSD?
	         ▪ Which factors play a role in this?
	 • Do you experience a lot of stress at work?
	     ○ What is the contribution of BPSD?
	     ○ Are people more stressed when you are also stressed?
	 • Statement: By providing insight into the stress level in people with dementia, the workload decreases.
	 • Statement: Healthcare professionals should also wear a stress meter.
	 Statement: As little technology as possible should be used in healthcare

60-75	Break
75-100	How does the ideal wearable sensor look like? Participants write down their opinion on post-its. This assignment is performed in groups of 2 to 3 persons.
100-140	Each group presents their opinion, based upon the post-its, regarding the design of the wearable sensor. Post-its were collected on a central board. After each group presented, participants reflected on all the post-its. During this phase, new ideas or needs were also added on a post-it.
140-150	Focus group was finished.

APPENDIX III: THE SECOND FOCUS GROUP (CONSISTING OF (IN)FORMAL CAREGIVERS AND COMMUNITY-DWELLING PEOPLE WITH DEMENTIA)

The following schedule was used while conducting the second focus group. Depending on the participant's answer, questions could be rephrased or specific follow-up questions could be asked. The exact language use was adapted to the participant, in which also the nature of the relationship with the resident was considered.

Time (minutes)	Activity
0-5	Researchers (n=3) and participants (n=14) introduced themselves shortly
5-10	Starting the interaction regarding wearables: a fit bit (expected to be known by most people) was shown. Who knows the fit bit?
10-20	The Empatica E4 explained and shown. Each participant got to hold the Empatica. The following questions were asked: • What do you think of the design? • How does it feel
20-35	Multiple technologies were shown and explained, such as chest band and a chest-patch for measuring heart activity, and a sock for measuring skin conductance.
35-55	General discussion: what are the pros and cons per wearable? What would you use or not use, and why?
55-60	Focus group was finished.