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Challenges in collecting big data in a clinical environment with vulnerable population: Lessons learned from a study using a multi-modal sensors platform

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Abstract:	Agitation is one of the most common behavioural and psychological symptoms in people living with dementia (PLwD). This behaviour can cause tremendous stress and anxiety on family caregivers and healthcare providers. Direct observation of PLwD is the traditional way to measure episodes of agitation. However, this method is subjective, bias-prone and time-consuming. Importantly, it does not predict the onset of the agitation. Therefore, there is a need to develop a continuous monitoring system that can detect and/or predict the onset of agitation. In our study, we have set up a multi-modal sensor platform with video cameras, motion and door sensors, wristbands and pressure mats in a hospital-based dementia behavioural care unit to develop a predictive system to identify the onset of agitation. We have faced several barriers in the development and initiation of the study, namely addressing concerns about the study ethics, logistics and costs of study activities, device design for PLwD and limitations of its use in the hospital. In this paper, we discussed the strategies and methodologies we implemented to address these challenges for consideration by future researchers who will conduct similar studies in a hospital setting.

Response to reviewer's comments

Title page includes contact details of authors, abstract, keywords and acknowledgement

Title Page

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Keywords
Dementia; Agitation; Multi-modal Sensors; Ethics; Hospital; Lesson Learned

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Challenges in collecting big data in a clinical environment with vulnerable population: Lessons learned from a study using a multi-modal sensors platform

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Abstract – Agitation is one of the most common behavioural and psychological symptoms in people living with dementia (PLwD). This behaviour can cause tremendous stress and anxiety on family caregivers and healthcare providers. Direct observation of PLwD is the traditional way to measure episodes of agitation. However, this method is subjective, bias-prone and time-consuming. Importantly, it does not predict the onset of the agitation. Therefore, there is a need to develop a continuous monitoring system that can detect and/or predict the onset of agitation. In this study, a multi-modal sensor platform with video cameras, motion and door sensors, wristbands and pressure mats were set up in a hospital-based dementia behavioural care unit to develop a predictive system to identify the onset of agitation. The research team faced several barriers in the development and initiation of the study, namely addressing concerns about the study ethics, logistics and costs of study activities, device design for PLwD and limitations of its use in the hospital. In this paper, the strategies and methodologies that were implemented to address these challenges are discussed for consideration by future researchers who will conduct similar studies in a hospital setting.

Keywords

Dementia; Agitation; Multi-modal sensors; Hospital; Ethics; Lesson Learned

INTRODUCTION

Dementia is a chronic neurodegenerative condition with syndromes such as memory loss, disturbed behaviours and loss of motivation (World Health Organization, 2012). Age is one of the risk factors for developing dementia (World Health Organization, 2012). There is a global rise in the aging population due to low fertility rate and longer life expectancy (He, Goodkind, & Kowal, 2016), which means more people are facing the risk of living with dementia as they grow older. It was estimated that 47.5 million people would be living with dementia (PLwD) around the world in 2015 (Prince, Guerchet, & Prina, 2013), which will increase to 65.7 million by 2030 and 115.4 million by 2050 (Alzheimer's Disease International, 2009). Dementia imposes a huge impact on both those living with dementia and their primary care providers (World Health Organization, 2012).

Behavioural and psychological symptoms of dementia (BPSD) are among the most common of all the symptoms of dementia (Cerejeira, Lagarto, & Mukaetova-Ladinska, 2012). Agitation is one of the most prevalent of the BPSD (Cerejeira et al., 2012) and is usually present throughout the course of the condition (World Health Organization, 2012). Jiska Cohen-Mansfield and Nathan Billig define agitation as “inappropriate verbal, vocal, or motor activity that is not explained by needs or confusion per se” (1986, p.712). Agitated behaviours are often classified into four categories: physically aggressive behaviours, physically non-aggressive behaviours, verbally aggressive behaviours and verbally non-aggressive behaviours (Cohen-Mansfield & Billig, 1986; Cohen-Mansfield, Marx, & Rosenthal, 1989; Cohen-Mansfield, Werner, Watson, & Pasis, 1995). These behaviours can cause

tremendous stress, anxiety and burden in caregivers of PLwD (Cohen-Mansfield et al., 2010; Rocca et al., 2010), which can lead to the institutionalization of the person living with dementia (Cohen-Mansfield et al., 2010; Steele, Rovner, Chase, & Folstein, 1990; Volicer, Citrome, & Volavka, 2017).

Most episodes of agitation occur due to unmet needs and distress experienced by those with dementia (Cohen-Mansfield, 1999). For example, a person may exhibit agitation due to inability to express an immediate need, or due to a feeling of loneliness or discomfort (Alzheimer's Society, 2018). Assessment of agitation (its severity, frequency and pattern of expression) can help to identify underlying causes and the selection of appropriate interventions. Various assessment tools of agitation have been developed, such as the Pittsburgh Agitation Scale (PAS) (Rosen et al., 1994), and the Cohen-Mansfield Agitation Inventory (CMAI) (Cohen-Mansfield, 1991). These assessments are done via direct observation by either family caregivers or healthcare providers (Cohen-Mansfield, 1999; Gray, 2004). However, this observation method is not optimal given the subjectivity, time, recall bias, and costs involved (Cohen-Mansfield, 1999). Most importantly, these assessment tools are retrospective and cross-sectional, and not helpful at prospectively identifying patterns of behaviour. Therefore, it is important and valuable to develop an automatic, objective, and real-time and continuous monitoring system to track and detect episodes of agitation in people with dementia. With advancements in machine learning and predictive analytics, there are enormous opportunities to identify and predict the onset of agitation so that an appropriate intervention can be provided.

There are very few studies on detecting agitation in people with dementia using multi-modal sensing technologies in a real clinical setting (Khan et al., 2017). The systematic review by Shehroz Khan

and colleagues (2018) suggested that many previous studies reported correlation between actigraphy[1] and agitation among people with dementia and indicated that actigraphy has the potential to identify agitation in people with dementia. However, there is not much in the literature about the use of multi-modal sensing technologies to better detect agitation (Khan, Ye, Taati, & Mihailidis, 2018). In order to address this gap in the literature, the aim of the study presented in this paper is to develop a predictive system based on a multi-modal sensor platform that can automatically detect agitation[2] in people living with dementia employing machine learning and data mining techniques. The multi-modal sensor platform – **D**etection of **A**gitation and **A**ggression in PLw**D** (DAAD) – employs various sensing modalities to identify incidences of agitation (Khan et al., 2017). DAAD allows researchers to collect a novel source of rich patient information, such as his/her daily life activities (i.e., physical and physiological indicators, interactions with his/her surroundings), and sleep quality. The sensors employed in the DAAD framework could work in a complementary mode. For example, if an event is not captured by a sensing modality (i.e., camera), the event could potentially be captured by another modality (i.e., wristband) (Khan et al., 2017). These different sensing modalities provide more opportunities to determine the behavioural status of a person living with dementia (Khan et al., 2017) and allow researchers to find out the best way to develop a predictive system to determine the onset of agitation.

There are several technical challenges involved in using DAAD - in terms of data collection, data synchronization, data cleaning and data storage (Khan et al., 2017). In addition, the vulnerable population and the inpatient hospital setting add further complexity to the data collection. In this

[1] Actigraphy is a non-invasive method that monitors a person's activity/rest patterns over an extended period of time using a wearable device called Actigraph (Stone & Ancoli-Israel, 2011).

[2] In this paper, Jiska Cohen-Mansfield and Nathan Billig's (1986) classification of agitation was used, which includes both physically aggressive and non-aggressive behaviours, and verbally aggressive and non-aggressive behaviours (Cohen-Mansfield & Billig, 1986; Cohen-Mansfield et al., 1989; Cohen-Mansfield et al., 1995).

paper, the challenges that were encountered during the preparation of the study prior to and during patient data collection [which is on-going] are discussed. Specifically, the lessons learned and the difficulties encountered from three perspectives are underlined: 1) addressing ethical issues arising from this study; 2) logistics and cost of study implementation in an active and high-risk clinical environment; and 3) device design for use on a vulnerable population and limitations with its use in a hospital setting. By sharing the experiences and the learning process of the complexities of the study, this paper provides guidance and strategies for other researchers who are planning similar projects.

Overview of DAAD Platform Setup

The study presented in this paper is currently being conducted in a specialized dementia care inpatient unit located at the Toronto Rehabilitation Institute in Toronto, Ontario, Canada. This is a 17-bed short-stay unit (mean length of stay is 60 days) for individuals with dementia experiencing severe BPSD. The multi-modal sensor platform installed on the inpatient unit includes: 1) video cameras, 2) a wristband – E4 Empatica (Empatica, 2018), 3) pressure mats – SleepIQ Labs (SleepIQ Labs, 2018), and 4) motion and contact/door sensors (INSTEON, 2018). A brief description of these different sensors is presented below:

1) Video cameras: Fifteen video cameras are installed in the ceilings of common areas of the specialized dementia care inpatient unit, including hallways, the dining room and the lounge room (See Figure 1). The video data are used for labeling the incidences of agitation of a patient participant based on incidences documented by nurses (i.e., the location and the time of the incident, and the description of the incidence of agitation of a patient). The cameras are programmed to record videos between 7am and 11pm.

Figure 1 here

2) E4 Empatica (Empatica, 2018): A wearable wristband is worn by a patient participant to record his/her acceleration data and physiological information including heart rate and body movements. The wristband is applied to the dominant wrist every morning or after a morning shower, and taken off by the nurse before the patient goes to bed at night.

3) Pressure mats (SleepIQ Labs, 2018): The mats are placed under the mattresses of the patients' beds. They are used to record a patient's sleep pattern, sleep quality and physiological information, such as heart rate and respiratory rate.

4) Motion and door sensors (INSTEON, 2018): These sensors are installed in the patient's washroom area. Each washroom has two motion sensors installed by the sink and the toilet respectively. The door sensor is installed on the washroom door. These sensors detect a person's presence and absence in the washroom, and opening or closing of the washroom door.

ADDRESSING ETHICAL ISSUES ARISING FROM THE STUDY

The use of video cameras to capture images and activities of various stakeholders including unit residents, staff and visitors in the unit public area presented challenges in the ethical design of this study. The research team was invited to a research ethics full board meeting a few months after the initial ethics application submission. The committee members perceived the study as very intrusive due to the use of the video cameras. They felt the use of cameras posed a potential harm, presenting significant implications for privacy of stakeholders in the unit (i.e., staff, residents, and visitors)

especially for people who are not able to give consent as a result of lack of decision-making capacity (Broyles, Tate, & Happ, 2008; Petrini, 2011). The video-recordings contain identifiable information, which enhances the risks of disclosure of privacy and confidentiality. The following sub-sections describe the three key concerns raised by the Research Ethics Board (REB) and how the research team incorporated solutions to address these challenges. They are as follows: 1) recruitment and consent process; 2) privacy and confidentiality, and 3) participant's burden and incidental findings.

Recruitment and Consent Process

One of the main concerns in using video recording is obtaining informed consent from participants of the study (British Sociological Association, 2006; Broyles et al., 2008; Petrini, 2011; Prosser & Loxley, 2008; Wiles et al., 2008). Researchers need to make sure the participants are giving their consent in a voluntary manner (Prosser & Loxley, 2008). This is especially important when participants are unable to consent for themselves (Petrini, 2011). The participants in this study not only include patients who are residing in the unit, but also the unit staff (i.e., nurses, physicians, and housekeepers), and visitors.

Education Session and Informed Consent with Staff

Since the video recordings were not limited specifically to patients residing in the unit, the REB highlighted the importance of providing appropriate education about the study (i.e., objectives of the study, procedures, rights, and confidentiality) to all stakeholders. Immediately after obtaining ethics approval, the research team started planning and coordinating education sessions on the unit. The project manager coordinated with the unit manager to organize the sessions for all unit staff. The unit staff were people who were working on the unit, including housekeepers, therapists, nursing staff,

physicians, nursing students, volunteers, dietitians, pharmacists, program managers, clinical nursing specialists, nurse practitioners, social workers, administrative assistants, therapeutic recreationists, and advance practice nurse educators. About eight education sessions were conducted by a team of researchers over four weeks in the unit in order to enroll all the unit staff. The majority of the sessions were conducted during the day. One education session was conducted at night for the night shift nurses. The education session included information on the study objectives, study procedures, the purpose of using the video cameras and other sensors, and contact information of the research team. The education sessions not only gathered the unit staff with the researchers, but also engaged staff to participate in the study and offered opportunities to provide feedback and share their concerns about the study with the research team. Initially, the video cameras, with voice recording functionality enabled, were proposed to be installed inside patient rooms during the study. However, this was considered to be too intrusive and caused discomfort among the nurses. With the nurses' feedback, the research team decided not to install cameras inside any patient rooms and to disable the voice recording function of the cameras.

The consent forms were distributed to the staff after the education sessions. A consent box was created and placed in the nurses' station. Staff's decision whether to participate in the study was indicated by signing the consent form. Researchers would check and collect the forms periodically (i.e., twice a week). The unit manager provided a list of current unit staff so that the research team could note the staff members who provided informed consent. The unit manager and a clinician researcher on the team helped introduce the study to the current staff and the new hires, as well as connecting the staff with the researchers for informed consent. A researcher coordinated with the unit manager for any new hires, including nursing students, residents, volunteers, and nursing staff,

requesting a list of new hires periodically from the unit manager. The researcher would then discuss the study with the new hires during their shift and get their consent. In addition, the researcher from the team would come to the unit twice a day during the weekdays. For any new people not previously identified, the researcher would approach and talk to them about the study and get their consent. For any staff who were very infrequently on the unit (a few times a year or less), they would be regarded as a visitor. Please refer to the section below for detail on obtaining consent from visitors.

The research team emphasized the voluntary nature of participation in the research protocol, consent form, and other related ethics documents. The staff could withdraw from the study at any time without providing a reason and could refuse to participate in the study without any impact on their employment status. "Processual consent" (Rosenblatt, 1995) (p.148) was applied throughout the study. Different from the traditional informed consent that primarily occurs prior to the start of the data collection, "processual consent" continuously occurs during the study (Rosenblatt, 1995). The research team made the contact information available at the nurses' station on the unit. Staff was encouraged to contact the researchers for any questions related to the study. If they initially agreed to participate in the study and then changed their mind during the data collection, they could either contact researchers about it or sign the consent form again by checking the non-consent option. Spare consent forms were made available in the consent box in the nurses' station. A researcher was also available during the data collection period twice a day (i.e., morning and afternoon) on the unit to answer any questions and concerns from the nurses.

To help with recruitment and staff participation, the research team particularly stressed the purpose of the use of the video cameras during the education session. The research team assured the unit staff

that the cameras were not used for staff monitoring nor evaluation of their performance or abilities in any way. The cameras were only used for annotating data collected from other sensors to help in the development of the machine learning algorithms for detecting and predicting agitated behaviours in those with dementia. The staff was also assured that their images would not be used in any presentation and /or publication of results outside the research team. The staff was informed that no one who worked on the unit in a clinical capacity, including the manager and clinician researcher, would have access to the video data. The unit manager and the clinician researcher are the only research team members who are working on the unit who do not have access to the video data. The study project manager who is overseeing the data collection will make sure that none of the staff who work on the unit will have access to the video data during or after data collection periods. This information is also clearly indicated in the protocol and the consent forms. The video data will only be accessible to select research team members, including a project lead scientist, a post-doctoral fellow and a research assistant who are analyzing the data, and the project manager who is managing the data.

The REB raised a question about handling situations when a staff does not want to be video recorded. To address the REB's concern, it was made clear to non-consenting staff that their video data would not be analyzed, used or published for any purposes. Only video data from consented patient participants would be analyzed. Given that video cameras continuously record during certain hours, it was not practical to stop the recording. Upon completion of data collection at the conclusion of the study, the video recordings during the periods when non-consenting staff were working would be deleted. Researchers recorded the non-consenting staff's working schedules to ensure that the video

recordings made during those periods would be deleted. This was emphasized in the education sessions, as well as in the staff consent form.

Informed Consent with Substitute Decision Maker (SDM)

One issue with the study using video cameras is the capacity of a vulnerable person to give valid informed consent (Petrini, 2011). The patients who stay in the unit have advanced dementia, and are routinely assessed for capacity around decision-making at the start of their admissions. The clinician-researcher would confirm the (in)capacity of the individual with regards to consenting to a research study. The clinician researcher would confirm with the substitute decision-maker (SDM)[3] that they would agree to be contacted by a researcher about a potential study. Then, the potential patient participant's SDM was approached and asked to give consent on behalf of the patient. SDMs were given ample time (i.e. up to four weeks) to review the study information to decide whether to enroll in the study (General Medical Council, 2002; Parry, Pino, Faull, & Feathers, 2016).

The patient enrolled in the study would need to wear a wristband during data collection, and this required the patient's physical assent. Patients were not approached for verbal assent due to the advanced stage of dementia. However, they were closely monitored for signs of dissent to wearing the wristband. If a patient refused to wear the wristband, the nurse would re-approach to try and apply the wristband at a later time or on the next day. If the patient consistently showed dissent over the course of a week, then the patient would be withdrawn from the study. In order to monitor a patient's willingness to wear the wristband, the patient's assigned nurse would routinely check on the patient to assess his/her comfort level in wearing the wristband in the study. Again, the patient's

[3] SDM refers to a patient's legally authorized representative (LAR) who has the Power of Attorney (POA) for a patient's treatment or personal care. The term SDM is used in this paper in order to keep consistent with the REB documentation.

voluntary participation was ensured by making researchers' contact information available in the unit, reminding the patient's assigned nurse to check the patient's comfort level in wearing the wristband, and assigning a research staff member to offer continuous support on the unit (i.e., visit unit twice a day) during the data collection period.

To inform future patients and their SDMs, the project manager coordinated with the admissions coordinator and unit administrator to send out the study introductory letter along with the admission and bed offer letters to the SDM two weeks prior to the date of study commencement. The introductory letter provided information such as the purpose of the study, the purpose of using the video cameras and researchers' contact information. This is to inform future patients and their SDMs of the study prior to the patients' admission.

Informed Consent with Visitors

Another question raised by the REB was about managing the situation when not all visitors agree to be video recorded. As the video recordings occurred continuously, there was no way not to capture non-consenting individuals in the recordings. It was not feasible to obtain informed consent from every visitor to the unit (British Sociological Association, 2006; Prosser & Loxley, 2008; Wiles et al., 2008). In order to proactively protect their interests and rights, researchers posted recording notices in the unit two weeks prior to the commencement of the study period and the notices have remained in place during the current data collection period. The notices were posted at locations where they were easily visible by the visitors and unit staff. Visitors who were opposed to being recorded on the unit were asked to contact researchers with the date and time of their visit. These recordings will then be deleted by a research coordinator immediately after the data collection period

at the end of the study. In the study, child visitors were not asked for assent. Their parents/guardians would make decisions on behalf of the child visitors. If their parents/guardians did not feel comfortable to have their child video recorded, they would be encouraged to contact the researchers of the date and time of their visit. These recordings will be deleted by the project manager after the data collection period at the end of the study.

Currently, the data collection is still ongoing. To date, unit staff and visitors have been very supportive of the project. None of the participants have withdrawn/been withdrawn from the study. Ninety-six unit staff have been approached. Only one staff member did not agree to participate in the study. None of the visitors have opposed the study or expressed any concerns about the video recordings. For potential patient participants, 22 SDMs have been approached to date, with 11 SDMs agreeing to participate in the study on behalf of the patients. There were no questions or concerns raised by the participants that were not considered during the study design. Some SDMs were interested in getting a copy of the project results. Some SDMs expressed concern about whether the patient would be identified when the results were published. Researchers assured SDMs that all images would be de-identified as described below.

Privacy and Confidentiality

Another ethical challenge of using the video recording is that it could pose potential risks to the participant's privacy (Broyles et al., 2008; Parry et al., 2016; Petrini, 2011). Images of the people from the video will not be de-identified. Faces of people from the recordings could be recognized. Thus, there are potential risks that the participant's privacy and confidentiality might be violated (Broyles et al., 2008; Kelly et al., 2013; Parry et al., 2016).

REB requested details regarding the measures to be taken to ensure the privacy and confidentiality of the data captured and collected for the study. Specifically, a) the location of the data storage and its encryption; b) procedures for minimizing the potential harms if personal health information were disclosed to an unauthorized party; c) the length of data retention; d) identification of people with access to the data; e) explanations of how to manage data of participants who either withdraw from the study or who are withdrawn from the study by the researchers.

The research team provided appropriate solutions to address the above issues to minimize the risks of breaching an individual's privacy and confidentiality. To assure the data was securely stored, all the data were kept on the hospital servers, which were already encrypted and secured by the hospital Information Technology staff with password protection. The hospital research server cannot be accessed from outside networks or internet, and clinical staff do not have access to it. The electronic files that contained participants' personal information, and agitation events information, were also password protected with only specific research staff (i.e., research assistant, lead project scientist, and project manager) knowing the password. Among all the collected data, video data was of the most concern because individuals could be identified. The video recordings were originally stored in a Digital Video Recorder (DVR) that was placed in a secure location in the nurses' station. However, the internal storage of the DVR was only 500 GB. It would be labor intensive and time-consuming to transfer every 500 GB (i.e., equivalent to six days of video recording) to the hospital servers. To solve the problem, the research team set up a password protected File Transfer Protocol (FTP) transfer mechanism that can seamlessly transfer the data from the cameras to the designated encrypted hospital server directly. Compared to other methods of data transmission (i.e.,

downloading recordings from the DVR to an external hard drive and then uploading the data from the external hard drive to the server), the FTP transfer allowed data to be directly stored on the server. As a result, this approach minimized the risks of data loss and exposure to an unauthorized third party. In addition, the patient participant was assigned a random code number and all data in the study was labeled with this number to maintain anonymity. All collected data will be stored on the hospital servers for five years after the study closure with access restricted to the research team specifically involved in this study, excluding the unit manager and clinician researcher.

All participants were assured that their faces, names and other features that could disclose their identity would be de-identified by blocking out their faces and any other distinguishing features prior to any study dissemination activities, such as presentations and/or publications. As the video recordings could potentially be used for secondary analysis (i.e., algorithms validation), this was addressed in the consent forms wherein permission was obtained to use the recordings for other similar studies. In the event of withdrawal or being withdrawn, the participant would be informed that their data would not be included in the data analysis after their voluntary withdrawal or after being withdrawn by study personnel. Given that video cameras continuously record, there is no way to stop the video recordings during the data collection period. Their recordings will be deleted after study data collection was concluded at the end of the study.

In addition, the research team attempted to maximize privacy protection of various stakeholders and limit intrusions by video recording only the common areas of the unit where patients usually spend their day (i.e., hallways, dining, and lounge room). There were no cameras installed in the patient's room, bathroom, shower room, staff's meeting room, and nurses' station. As per the request from the

staff, video recording from the night shift (11 pm to 7 am) was omitted. Additionally, the audio recording from all cameras was turned off and not used during the data collection phase of the study.

Staff Participation Burden and Incidental Findings

The potential risks of the breach of privacy and confidentiality may result in anxiety and burden for the unit staff, which can deter them from participating in the study (Broyles et al., 2008). Staff may worry about the recordings being viewed and criticized by their peers or superiors (Adomat, 1999; Broyles et al., 2008). They may fear the use of the recordings for legal purposes and use of the cameras as a tool to monitor their general conduct or behaviours in the unit (Adomat, 1999). However, researchers have also suggested that participants will get used to the camera over time and will not be affected by its presence (Arborelius & Timpka, 1990; Carroll, Iedema, & Kerridge, 2008; Latvala, Vuokila-Oikkonen, & Janhonen, 2000).

REB requested detailed explanations on the analysis and usage of data, and raised concerns about the actions to be taken for incidental findings. To address the REB's request, the research team established that video recordings were only used for the development of the algorithms for the predictive system. The cameras were installed in the unit adjacent to the already existing security cameras. They were not meant to be used for patient and/or staff monitoring. The research team asserted that only data from consenting patient participants would be analyzed. Video data from non-consenting individuals would not be analyzed, used or published for any purposes. The video data was only used for data annotation to confirm and annotate a patient's episode of agitation based on the documentation from nurses. For instance, in a recording where consenting patient A became agitated because he/she was hit by a patient B (who is not part of the study) while they were sitting

together in the dining room, the analysis would focus only on the recordings of patient A; any behaviour exhibited by patient B would not be annotated or used. To be specific, the only data collected and analyzed in this example would be those relating to patient A. In this case, it would be noted that patient A was hit, as well as patient A's reaction towards being hit, such as shouting, crying or restlessly walking, but data would not include annotation of who hit him/her.

An important requirement set out by the REB was to have a clear plan for the management of any incidental findings when viewing the video recordings. An incidental finding is a finding that is out of a study's scope and may occur unexpectedly during the conduct of the research, and has the potential to cause a health concern to research participants (Wolf et al., 2008). There was also concern from the staff that the unit's established care practices, used to intervene to prevent harm due to aggressive behaviours, may be misinterpreted as abusive by research staff. To address both of these concerns, a process was established for researchers to follow should they observe any incident that they believed may represent physical or sexual abuse of the patient, based on definitions from the College of Nurses of Ontario (College of Nurses of Ontario, 2018). The staff participants consented to allow an experienced and trusted, but independent third party, familiar with best care practices in this area, to independently review any incidents of concern and provide guidance about whether the event would be reportable to the REB. Researchers also spent time on the unit and familiarized themselves with the typical behaviours of risk exhibited by the patients, and the established care practices in managing risky or aggressive behaviours.

In summary, although the use of the cameras poses several challenges, the benefits of using them as a data collection tool are significant. In fact, compared to traditional direct observation for agitation

events, camera recording has several advantages. It can provide more reliable and accurate records of the events (Caldwell & Atwal, 2005; Jewitt, 2012). It prevents recall bias often associated with human observation (Caldwell & Atwal, 2005; Jewitt, 2012). It records detailed on-going interactions between people, such as physical movement, and gestures (Caldwell & Atwal, 2005; Jewitt, 2012). The physical movement recordings can be reviewed repeatedly to make note of the occurrence, frequency and duration of agitated behaviour during the observation period (Caldwell & Atwal, 2005; Jewitt, 2012). With its advantages, video-recording has become increasingly popular in clinical research to examine a patient's behaviours, as well as a good medium for facilitating communication between patients and health professionals (Drew, Chatwin, & Collins, 2001; Petrini, 2011; Salmon & Young, 2011). A copy of the informed consent forms for the unit staff and SDMs, and a copy of the recording notice from the study have been included in this manuscript for future researchers to help them develop similar studies using video cameras.

LOGISTICS AND COST OF STUDY COMMENCEMENT

The first step after ethics approval was staff recruitment via education sessions. The recruitment was labor intensive, given the consent process was ongoing with the new hires and the number of individuals working on the unit (some for only a few shifts a month). The initial consent process took over six months (See Table 1). Table 1 shows the timeline of several tasks prior to the start of the study. It also highlights the delays incurred in executing some of those activities.

Table 1 here

Prior to the decision of purchasing the E4 Empatica (Empatica, 2018), several comparisons with other wristbands were made. E4 was eventually chosen because it allowed access to raw data at real-

time for algorithms development. Many other wristbands (i.e., Fitbit and Angel) did not allow raw data access or did not store the raw data locally on the device. Furthermore, the E4 wristband allowed simultaneous collection of both the physiological and acceleration information without other accessories (i.e., phone or a strap to wrap around the chest). For example, for the ActiGraph (ActiGraph, 2018), a strap was needed to tie and strap around the chest for heart rate monitoring. This was not feasible in this study and could cause discomfort for the patient population. As a result, the ActiGraph was not used in this study.

INSTEON motion and door sensors were chosen for the study (INSTEON, 2018). The purpose of these sensors is to record a patient's motion in a room and its correlation to the agitation. However, these sensors will capture anyone (i.e., other patients who do not reside in that room, or nurses or housekeepers) who goes into the room, which makes it hard to identify the patient participant who is residing in that room. A lesson learned from this study is that there is a need for a patient identifying or locating system in conjunction with other sensors. An example of a possible solution would be the use of radio-frequency identification (RFID) tags to identify which patients are in the vicinity when a sensor is activated.

After the equipment purchase, the next step was the installation of cameras in the unit. The installation was complex and involved consultation with several organizational departments, including the electrical, security, infection control, and facility operations managers. The cameras were installed in the locations adjacent to the existing security cameras (See Figure 1). Therefore, the security manager needed to be informed and to approve the locations of those cameras so as not to obstruct the view of the security cameras. In order to gain permission for installation, an Activity

Permit needed to be completed and approved first by the Contact Infection Control Practitioner. This was to ensure the operation was in safety compliance in accordance with the hospital policies and procedures. The camera installation also involved the use of the containment tent to prevent contamination and hazardous materials which required two people (electrician and a helper) on site.

The installation took approximately five months to complete. It only took place in the early mornings when the staff had not started working and patients were still asleep. In this case, only one qualified electrician could complete the installation due to his familiarity with the unit. Thus, the installation work was delayed for a month until the electrician was available. Other work delay was also experienced including the purchase of the missing fire-rated cables, cable extensions and other supplies that were required for the camera installation.

A pilot study with the team members was conducted for a week prior to the data collection in order to test all the equipment. Following the pilot study, several training sessions with the nurses were conducted. The data collection requires help from nurses. The nurses are asked to put the wristband on the patients and to charge it every night. In order to help us identify the incidences of agitation, the healthcare providers (e.g. predominantly nurses) are asked to label those periods during their daily documentation on patient's clinical chart. To help with visualization, the agitated event is labeled with a green sticker in the clinical chart. The event is also documented with its time and location to facilitate review of the video recording. In coordination with the unit manager, the research team gave presentations during education sessions with the healthcare providers about the procedures for charging the wristband and documenting the incidences of agitation. During the data collection period, a researcher comes to the unit every day to check the equipment to ensure it is

functioning appropriately as well as to remind the assigned nurse of the patient participants with respect to the data collection procedures. To make sure all the cameras are working properly during the data collection, a researcher regularly (twice a week) monitors the cameras from a remote software application. In the case that there are no patients participating in the study, the cameras are turned off. Once the data collection is finished at the end of the study, researchers will ensure the cameras are disabled by unplugging the cameras' cables from the DVR, removing the DVR from the nurses' station and storing the DVR in a secure locked cabinet located in the laboratory. Data annotation is completed by three members of the research team. Two researchers review the patient's chart and record the incidences of agitation. A graduate nursing student then reviews the video data to fine-tune the labels of those events. The housekeeper was also asked to help check the pressure mat cable periodically to ensure its connection is maintained.

There were three main costs for the study: the wristband, camera installation, and hospital storage space for the video recordings.

Camera Installation Cost

In addition to the cost of hiring the electrician, there was an unexpected cost on additional items for the camera installation. The cameras need to be installed throughout the unit; thus, cable extensions were required. The required cables used in the hospital needed to be fire-rated. The use of the containment tent was also required. The research team was able to rent the tent from the hospital, which helped lower the costs.

Storage Space Cost

Video cameras can generate a large amount of data. In this case, it required about 80 GB per day (from 7 am to 11 pm). Thus, a large storage space needed to be purchased for the video data. If the server space was not large enough, additional cost of server space would be required. Tape backup was used as an option to store the existing video recordings as it allowed for more storage space for new recordings.

DEVICE DESIGN AND LIMITATIONS

When implementing the study, it became essential to consider digital capacity of the hospital environment. There are advantages to using devices connected via wireless network as they reduce the usage of cables, provide more flexibility in placing the devices, and allow controlling the devices remotely. However, there are several limitations to using these devices, which are network stability, signal strength and signal range. First, the stability of the network should be carefully considered. With advanced technologies, more and more devices are connected wirelessly via the hospital network. As a result of the network competition, it might take longer time to connect or can result in lost connection at times. If the hospital network is disabled or not accessible, the connection will be disturbed and thus can lead to significant missing data that will be detrimental for building predictive models. In this study, the wireless network is needed to a) automatically transfer the video data from the cameras to a secured hospital server, b) transfer the pressure mat data to a secure cloud for storage, and c) send motion and door sensor alerts to a secured email account that is specially created for this purpose.

Second is the signal strength. In this project, there are six wireless cameras installed. However, the images from these cameras are choppy during the recording, which could be due to poor signal strength. One particular wireless camera freezes regularly, which might lead to data loss. As a consequence, all the cameras need to be monitored regularly and reset to resolve the issue.

Lastly, the signal range should be considered when using wireless devices in a hospital. A network booster might be needed to enhance the signal coverage. The motion and door sensors were connected wirelessly to a central processing device, called Hub. The Hub was placed in the nurses' station that was in the middle of the unit. A poor signal or no signal occurred when the sensors were installed in both ends of the unit. To solve the issue, a Range Extender (INSTEON, 2018) was used to amplify the wireless signal and to extend the signal coverage (INSTEON, 2018).

The patients in the unit have a tendency of pulling and moving objects around. Therefore, the devices can only be placed in locations out of reach or out of sight. In this study, the pressure mat is connected to a Device Network Box (See Figure 2) via a USB cable. The box is big and is visible to patients; thus, it had to be placed in the outlets behind the patient's bed. The research team has experienced trouble finding a good location to place the Range Extender. Although there are wall outlets in the hallway in the unit, they cannot be used due to the safety concerns of the patients (i.e., if a device was pulled by the patients). The Range Extender needed to be plugged in a locked room (i.e., kitchen, and staff meeting room), which is out of reach of the patients.

Figure 2 here

The cameras used in the study were analog. Compared to digital cameras, the images of the analog cameras were pixelated. These cameras also came with night vision. The original plan with the night vision cameras was to record events that happened during night time. The images with the night vision were black and white. The issue with the night vision cameras was that it switched to its night vision mode during the day time when the lighting conditions were low. This resulted in the images being even harder to see and annotate agitation events.

A wristband E4 Empatica (Empatica, 2018) was used for physiological information collection. Some design issues were encountered while using it. First, the wristband was easily taken off by the patients and was hard to put on. To help secure the band, two "O-Rings" were attached on it (See Figure 3). The band needed to be pressed hard to be put on, which could pinch a patient's skin. The issue could be resolved by putting a finger underneath the band when pressing the band. This way, it prevented the patient's skin from contacting the band when it was pressed. Second, the wristband was not water-proof. As a result, it had to be taken off before showering, resulting in missed data collection if an episode of agitation occurred during the shower. Third, the wristband needed to be worn tightly to obtain good quality data. However, this may cause discomfort for patients. Lastly, the wristband had a short battery life and small internal data storage space. Therefore, it needed to be taken off for charging and data transfer every day, which inevitably interfered with data collection. To minimize the data interruption, the nurses charge the wristband every night before the patient goes to bed. A researcher comes to the unit every morning to download the data and then puts it on the patients for the next day data collection. If the patient is scheduled for a shower, the wristband is placed on after the shower in the morning. The Recreational Therapists on the unit were trained to download the data and help with data collection on weekends.

Figure 3 here

CONCLUSION

Researchers should know and understand the potential challenges in collecting big data via cameras with vulnerable participants in a hospital so that they can plan ahead and minimize avoidable issues that may arise. As such, this paper provides detailed methodologies adopted to resolve encountered obstacles, and highlights the methods to lower costs and equipment over-runs. These experiences in a clinical setting could be helpful to other researchers.

Collaboration with the unit manager and having a clinician-researcher co-investigator on the research team were both important factors. Their support was important to successful recruitment of staff participants. They play an important role in connecting the researchers with the unit staff, and explaining the project to the staff and new hires. It is important to not just recruit and ask nurses to perform specific tasks pertinent to the study, but also to engage them to be part of the planning of study implementation that will affect workload and need to accommodate for patient care. For example, from the nurses' suggestions, an easy-access wristband charging station was provided; application of the wristband was postponed on shower days; a reminder note of patients who were currently involved in the study to remind nurses was regularly updated; cameras from the patient's room were removed, and the audio recording function was disabled during the video data collection period. By engaging the staff, it established a relationship of trust with the researchers. This, in turn, assisted the recruitment and data collection. It is essential to have a research coordinator on-board with capacity to support and negotiate with staff members, educate others to manage digital devices and engage in in-the-moment problem-solving.

In summary, collecting big data using multi-modal sensors in a hospital with a vulnerable population requires a detailed, thoughtful, and time-intensive planning strategy. First, one must identify all potential stakeholders who will be impacted by the study, then collaborate with them to develop a thorough research design and approach to data collection to protect the privacy and confidentiality and ensure the voluntary participation of various stakeholders. Second, the participant recruitment is labour intensive and lengthy, given that anyone who works on or visits the unit is considered a participant. Third, using video recordings as a data collection tool is expensive. Camera installation in a hospital is complex and costly. The large dataset generated from the video recordings requires a large storage space, which requires a big portion of the budget. To analyze the rich data from the video recordings is also labour intensive and time-consuming. There is not only the physical cost of the materials and the labour, but also the time involved in completing the tasks. Therefore, researchers should consider these costs when writing and submitting the grant proposal. The successful data collection involves various partners (i.e., nurses' help with wristband charging, equipment monitoring during data collection from researchers, clear documentation of the incidences of agitation from nurses, and the help from the housekeepers to monitor the pressure mat connection). Fourth, there are limitations with regards to using the wireless devices in a hospital. Researchers need to consider the network stability, signal strength and range of the wireless connection when planning to use them. Fifth, due to the target population (i.e., people with dementia with potential risks of agitation), a thoughtful device selection process is required. Using the wristband as an example, researchers should consider the effectiveness and ease of its use for patients and application challenges for staff. A universal design of the device might be considered for the device developer. A device should embrace a more inclusive design (i.e., easy to be put on, water

proof, and long battery life) if it were going to be used by an older, and vulnerable population with behavioural symptoms.

As reported in this paper, DAAD (Khan et al., 2017) is one of the first multi-modal sensing platforms installed in a clinical environment to detect the onset of agitation in people with dementia. Addressing the ethical concerns raised by this study was the first challenge. However, with thoughtful planning and detailed protocols that respect all stakeholders' privacy and confidentiality, ensure stakeholders' voluntary consent, and provide direction for the reporting of possible incidental findings, it is feasible to use video-recording as a data collection tool in a hospital setting. This paper has explicitly outlined the methods in addressing these ethical issues for other researchers to learn from.

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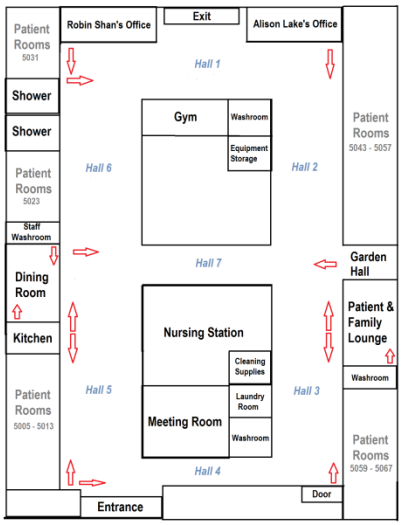

Figure 1. Layout of the specialized dementia care inpatient unit map. The red arrows represent the camera's locations.

Figure 2. Device Network Box

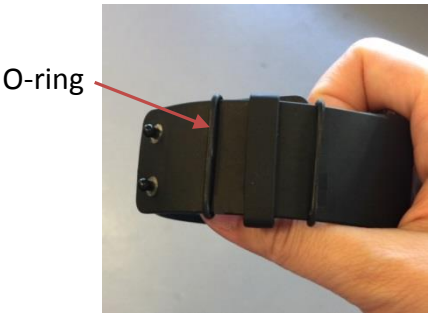

Figure 3. O-rings attached to the wristband

Table 1. Timeline of the tasks prior to the commencement of data collection

Tasks	**Time period spent for each task**
Gaining ethics approval	1 year
Education sessions with staff	4 weeks
Initial staff recruitment	6 months and it is ongoing thorough the data collection
Video cameras installation	5 months
Pilot study	1 week
Nurses training for data collection	2 weeks

Information and Consent Form for Clinical Staff to Participate in a Research Study

Title of the Study:

Detecting behavioral and psychological symptoms of dementia using multimodal sensors

Faculty Supervisor: xxx

(Principal Investigator) Ph: xxx

Email: xxx

Research Manager: xxx

Ph: xxx

Email: xxx

Please note that the security of e-mail messages is not guaranteed. Messages may be forged, forwarded, kept indefinitely, or seen by others using the internet. Do not use e-mail to discuss information you think is sensitive. Do not use e-mail in an emergency since e-mail may be delayed.

Sponsor

The study is funded by xxx.

Introduction

You are being asked to take part in a research study as someone who works on the Geriatric Psychiatric Unit at Toronto Rehabilitation Institute (TRI). Please read this explanation about the study and its risks and benefits before you decide if you would like to take part. You may take up to four weeks to decide whether or not to participate. You should ask the researchers to explain anything that you do not understand and make sure that all of your questions have been answered before signing this consent form. Before you make your decision, feel free to talk about this study with anyone you wish including your friends and family. Participation in this study is voluntary.

Background/Purpose of the Study

Aggression and agitation are very common behaviors among people with dementia. These behaviors can be stressful both for the people with dementia and the people caring for them. In the study, we are developing a computer-based system to recognize patient factors that may cause aggression and agitation in persons with dementia.

We are inviting you to participate in a research study to collect the data needed to build this computer-based system.

You are being asked to participate because you are a staff working in the Geriatric Psychiatric Unit at Toronto Rehabilitation Institute (TRI). The study is planning to install cameras in the common areas to record the patient's daily life. You might be recorded by the cameras because you are working on the unit.

We will be recruiting up to twenty people with dementia from the unit for the study. Prior to commencing recruitment of the patients, we would like to know whether you agree to participate in this study. If you agree to participation, you may change your mind at any time.

Description of the Research Study

Study Design

The study will be using video cameras and some other devices (described in Table 1, below) to observe and record a patient's life in the unit. These recorded data will help us understand some of the factors that could trigger the aggression and/or agitation in persons with dementia.

Study Setup

Video cameras will be installed in the common areas of the unit including two main hall ways, the dinning [sic]/activity room, and the patient and family lounge. Sensors will also be placed in patient's room with the patient's agreement and/or SDM's agreement. The purpose of the use of these devices is to record his/her interactions with people and his/her environment.

Figures 1, 2 and 3 show the examples of images captured by the video cameras from different angles of the dining/activity room, the lounge and the hall ways respectively. The devices that will be used in the patient's room and their purposes are indicated in Table 1.

Table 1. Devices that will be used in the study and their purposes

Devices	Purpose
Infrared (motion) sensors (please see Figure 4)	Infrared sensors detect motion but do not collect images. They will help detect motion in and out of patient rooms.
Contact sensors (please see Figure 5)	Contact sensors on the doors of a patient's room and on cabinet drawers will track opening/closing.
Pressure sensors (please see Figure 6)	The pressure sensors tracks a patient's heart rate, breathing rate, sleep duration, restlessness, and in and out of bed events. They will be placed under the mattress.
Wristband sensors (please see Figure 7)	Wristband sensors track the patient's physical activity, heart rate, and pulse.
Video cameras	Video cameras capture the patients' movements, facial expression and physical behaviors in common areas of the unit.

Figure 1. Example of pictures captured in the dining/activity room from different angles in the Geriatric Psychiatric Unit.

Figure 2. Example of pictures captured in the family and patient lounge room from different angles in the Geriatric Psychiatric Unit.

Figure 3. Example of pictures captured in the hall ways from different angles in the Geriatric Psychiatric Unit.

Figure 4. Example of an infrared (motion) sensor

Figure 5. Example of a contact sensor

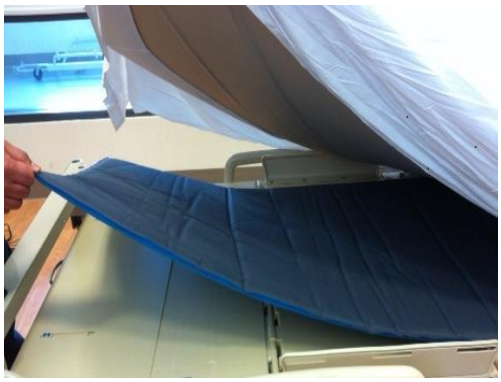

Figure 6. Example of a pressure sensor placed under the mattress

Figure 7 Example of a wristband sensor

Recording/Study Period

The study period will last until we collect data from twenty patients on the unit. A researcher will be responsible for the operation of the devices and will check them daily to ensure they are running correctly.

What will Happen During the Study

As a staff member on 5 South, you are not required to perform any additional tasks or activities during the study. We are only asking for your consent to record you on the study video cameras as you carry out your work. It is important to know the following information about the video data collected:

1) Although the cameras will be recording continuously every day between 7am and 11pm, the researchers will only review brief segments of the video around the time of aggressive episodes. The time and location of aggressive incidents will be identified from chart reviews and the episode viewed to note the timing and type of aggressive event. There will be no sound or voice recording.

2) The annotation of the video will comment only on patient behaviours and their context, but will not comment on staff behaviours. For example, the annotation may say that the patient was receiving assistance to walk, or that they were being fed, but would not provide descriptions or evaluations of the staff actions.
3) Individual staff members will not be identified by name or any other descriptors in the data collection
4) The cameras in the common areas will be located in areas on the unit where staff members are already recorded by security cameras.
5) If you are involved in an event that you don't want viewed or analyzed by the researchers, you have the ability to provide researchers with the time and date of the event, and they will exclude it from the analysis.
6) All data collected for this research will remain strictly confidential. None of the clinical staff or managers from 5S will have access to this video data.
7) All data will be kept on an encrypted and password protected server used in the study and accessed only by the research team.
8) In the unlikely situation that, in the course of observing patient behaviour, the researcher observes a sexual or physical abuse of a patient, the researcher will consult with an independent third party, xxx, Professional Practice Chief for Occupational Therapy at xxx Health Sciences. xxx will provide guidance in determining if it is a reportable event, in which case the researchers will report the incident to UHN research ethics board.

Potential Harms/Risks

Anytime that there are video recordings, there is a risk of breach of confidentiality. We have put in place a number of safeguards to ensure that all data and information captured through this research is kept confidential to the researchers and that it is handled and stored in a safe and secure fashion. No information that may identify staff members will be shared outside of the research team. The researchers will work closely with you as well to identify any potential problems during the study.

Potential Benefits

You will not benefit directly from your participation in the study. Information learned from this study will be used by the researchers to build a system that can recognize some factors that cause aggression and agitation from the persons with dementia. This system may help people with dementia and caregivers in the future to manage aggression and aggravation.

Confidentiality

All data recorded during the study, whether you choose to participate or not, will be kept confidential and protected to the extent permitted by applicable laws. The study staff and the University Health Network Research Ethics Board (UHN REB) will have access to video recorded data for purposes associated with the study, but will only be allowed to access them under the supervision of the Principal Investigator xxx and will be obligated to protect your privacy and not disclose it to your colleagues or employers.

The computer that will be used to temporarily store the data will be encrypted and password protected to prevent any data breach or loss. All the data will be transferred to the UHN servers, which are encrypted and secure, for data analysis and long-term data storage. All data files will be kept strictly confidential within the research team and will not be shared with others without your express permission, with the exception of if sexual or physical abuse of a patient is recorded.

When the results of this study are published, your identity will not be disclosed. No staff images or names will be included in any reports, publications, or presentations that may come from this study.

The data for this study will be retained for five years after the date of study closure. All data will be destroyed five years after the date of study closure.

Voluntary Participation

Your participation in this study is voluntary. You may decide not to be in this study, or to be in the study now, and then change your mind later. You may leave the study at any time without affecting your future provision of health [sic], your relationship to the unit or your employment status at the unit. We will give you new information that is learned during the study that might affect your decision of whether to stay in the study.

Withdrawal from Study

If you decide to leave the study, you have the right to request withdrawal of information collected about yourself. Should you choose to withdraw from the study you are encouraged to contact Research Manager xxx at xxx or email xxx immediately.

If you leave the study, the information that was collected before you left the study will still be used in order to help answer the research question. No new information will be collected without your permission.

Costs and Reimbursement

There are no costs to participate in this study.

There is no monetary compensation or reimbursements for participation in this study.

Rights as a Participant

By signing this form you do not give up any of your legal rights against the investigators, sponsor or involved institutions for compensation, nor does this form relieve the investigators, sponsor or involved institutions of their legal and professional responsibilities.

Conflict of Interest

Researchers have an interest in completing this study. Their interests should not influence your decision of whether to participate in this study.

Commercialization

Should this research result in commercialization, UHN researchers intend to claim sole ownership of any results that would come from this study. You will not receive any financial benefit that might come from the results of this study.

Questions about the Study

If you have any questions, concerns or would like to speak to the study team for any reason, please contact Research Manager xxx at xxx or email xxx

If you have any questions about your rights as a research participant or have concerns about this study, call the Chair of the UHN REB or the Research Ethics office number at xxx. The REB is a group of people who oversee the ethical conduct of research studies. The UHN REB is not part of the study team. Everything that you discuss will be kept confidential.

You will be given a signed copy of this form.

Consent

This study has been explained to me and any questions I had have been answered.

I know that I may leave the study at any time. I agree to the use of video recordings as described in this form. I agree to take part in this study.

Print name of staff member	Date	Signature

My signature means that I have explained the study to the participant named above. I have answered all questions.

Print name of person who obtained consent	Date	Signature

Non-consent

The study has been explained to me and I decline to participate in full. In particular:

1) ☐ I do not want recordings of me in the common areas to be included in this research study. The researchers will not analyze video data from any shift that I have worked.

Information and Consent Form for Substitute Decision Maker in a Research Study

Title of the Study:

Detecting behavioral and psychological symptoms of dementia using multimodal sensors

Faculty Supervisor: xxx

(Principal Investigator) Ph: xxx

Email: xxx

Research Manager: xxx

Ph: xxx

Email: xxx

Please note that the security of e-mail messages is not guaranteed. Messages may be forged, forwarded, kept indefinitely, or seen by others using the internet. Do not use e-mail to discuss information you think is sensitive. Do not use e-mail in an emergency since e-mail may be delayed.

Sponsor

The study is funded by xxx.

Introduction

The person with dementia you are responsible for is being asked to take part in a research study. As his/her substitute decision maker (SDM), we would like to know if you will agree the person with dementia you are responsible for to participate in this research study as he/she would not be able to give consent him/herself. Please read this explanation about the study and its risks and benefits before you decide if you would like him/her to take part. You may take up to four weeks to decide whether or not you permit him/her participate [sic]. You should ask the researchers to explain anything that you do not understand and make sure that all of your questions have been answered before signing this consent form. Before you make your decision, feel free to talk about this study with anyone you wish including your friends, family, staff at UHN, and family doctor. Participation in this study is voluntary.

Background/Purpose of the Study

Aggression and agitation are very common behaviors among people with dementia. These behaviors can be stressful both for the people with dementia and the people caring for them. Aggression and agitation behaviors are usually observed and reported by the family caregivers and the institutional staff. However, this method can be very subjective and time consuming. In the study, we are developing a computer-based system that is able to recognize some factors that may cause aggression and agitation in persons with dementia. It is hoped that a deeper understanding of what causes aggression and agitation will help identify future ways to decrease the occurrence of aggression and agitation, thus reducing caregiver burden and increasing quality of life for the person with dementia.

We are inviting the person with dementia you provide substitute decision making for to participate in a research study that will collect the data we need to build the computer-based system.

We will be recruiting up to twenty people with dementia for the study.

The person with dementia you are responsible for is being asked to participate because he/she has been diagnosed with dementia and is currently staying in the Geriatric Psychiatric Unit at Toronto Rehabilitation Institute (TRI). As a substitute decision maker of the person with dementia, you decide whether he/she may participate in this study as he/she is not able to give legal consent him/herself. If you agree to participation, you may change your mind at any time. All participants in the study will be monitored for ongoing assent to participate; you will be informed if he/she demonstrates an unwillingness to participate.

Description of the Research Study

Study Design

The study will be using video cameras and some other devices (described in Table 1, below) to observe and record a patient's life in the unit. These recorded data will help us understand some of the factors that could trigger the aggression and/or agitation in persons with dementia.

Study Setup

If you agree to let the person you are responsible for participate in the study, a researcher from the research team will install some devices (as described in Table 1) in his/her room. The purpose of the use of these devices is to record his/her interactions with people and his/her environment. This,

in turn, will allow us to identify some possible factors that may cause any his/her aggressive and/or agitated behaviors.

Figures 1, 2 and 3 show the examples of images captured by the video cameras from different angles of the dining/activity room, the lounge and the hall ways respectively. The devices that will be used in the study and their purposes are indicated in Table 1.

As the Geriatric Psychiatric Unit is participating in this research, video cameras will be monitoring the common areas of the unit including two main hall ways, the dinning [sic]/activity room, and the patient and family lounge. If you choose for the person you are responsible for not to participate, then any images of him/her collected from these cameras will not be included in the research study.

Table 1. Devices that will be used in the study and their purposes

Devices	Purpose
Infrared (motion) sensors (please see Figure 4)	The purpose of the infrared sensors is to detect the locations of a patient in his/her room. The infrared sensors will be used to track the number of times a patient entering/going out the room and the times of the usage of the bathroom sink. They will be installed on the ceiling above the bathroom sink, and/or at the entrance of the individual room. The setup location may change depending on patient's preference. Motion sensors do not collect any images.
Contact sensors (please see Figure 5)	The purpose of the contact sensors is to track the number of times a patient uses his/her doors and cabinet drawers. The contact sensors will be installed on the doors of a patient's room, and/or on his/her cabinet drawers.

Pressure sensors (please see Figure 6)	The purpose of the pressure sensors is to track a patient's heart rate, breathing rate, sleep duration, restlessness, and in and out of bed events. They will be placed under the bed of a patient.
Wristband sensors (please see Figure 7)	The purpose of the wristband sensors is to track the patient's physical activity, heart rate, and pulse. The patient is encouraged to wear the wristband sensor all the time during the study.
Video cameras	The purpose of the video cameras is to capture the patient's life in the unit, which includes movements, emotions and physical behaviors of a patient when he/she is in the common areas of the unit including the dining/activity room, the lounge room and the hall ways. These areas are the places where patients will spend most of their time. Therefore, the video cameras will be installed on the ceilings at various locations of these areas.

Figure 1. Example of pictures captured in the dining/activity room from different angles in the Geriatric Psychiatric Unit.


Figure 2. Example of pictures captured in the family and patient lounge room from different angles in the Geriatric Psychiatric Unit.



Figure 3. Example of pictures captured in the hall ways from different angles in the Geriatric Psychiatric Unit.

Figure 4. Example of an infrared (motion) sensor

Figure 5. Example of a contact sensor

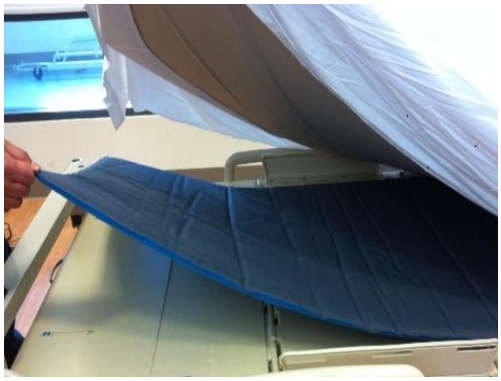

Figure 6. Example of a pressure sensor placed under the mattress

Figure 7. Example of a wristband sensor

The period of the study for the patient will be depending on his/her length of stay on the unit with a maximum two-month study period for each patient if his/her stay on the unit is longer than two months. If the patient is admitted to the unit for six weeks, the study period will be six weeks for him/her until he/she is discharged from the unit. A researcher will be responsible for the operation of the devices and will check them daily to ensure they are running correctly.

What will Happen During the Study

The video cameras in the common areas of the unit will be running twenty-four hours a day, seven days a week throughout the study period. The devices listed in Table 1 will be placed in the patient's room upon his/her agreement and your agreement. These devices in the patient's room will be running continuously during a patient's involvement in the study between 7am and 11pm a day, seven days a week. Note that video data collected that is not related to aggressive or agitated behaviors will not be used for analysis and will be deleted at the end of the data collection period.

As the Geriatric Psychiatric Unit is participating in this research, video cameras will be installed throughout the study in the hall ways, activity/dining room and the lounge room. You can ask for the patient to be opted out of any of the devices used in this research at any time.

If you agree to let the patient participate in the study, the researcher will also collect the patient's photo at the beginning of the study. The photo will only be used to positively identify that they are part of the research study when viewing the video.

The patient you are responsible for will also be asked to wear a wristband sensor (like a watch, see Figure 7) during the study. The wristband sensor will collect the heart rate and/or blood pressure of the patient, as well as his/her daily activity data, such as his/her movements. The patient is encouraged to wear it all the time during the study (except during the shower, bath time and charging time), but may take it off at any time. A researcher or a unit allied health worker will come every morning to check if the wristband is worn by the patient at the beginning of the day.

Apart from wearing the wristband sensor, the patient is not required to do anything in particular during the study. The devices installed in the patient's room as well as in the common areas of the

unit are only to record/observe the patient's life in the unit. These will be the data used to develop the system.

All data collected for this research will remain strictly confidential. No identifiable data will be shared outside of the research team. All data will be kept on an encrypted and password protected server used in the study and accessed only by the research team.

Potential Harms/Risks

There is a risk of breach of confidentiality due to the use of the video cameras. We will ensure that all data and information captured through this research is kept confidential to the study team and that it is handled and stored in a safe and secure fashion.

A computer will be placed on the unit during the study period to collect and temporarily store the data. This computer will be encrypted to prevent data breach by the unauthorized parties. The computer will also be password protected so that only the researchers from the research team can access the computer.

The researchers will work closely with the unit staff to identify any potential problems during the study.

No identifiable data will be shared outside of the study's research team.

Potential Benefits

The patient will not benefit directly from his/her participation in the study. Information learned from this study will be used by the researchers to build a system that can recognize some factors that cause aggression and agitation from the persons with dementia. This system may help people with dementia and caregivers in the future to manage aggression and aggravation.

Confidentiality

Personal Health Information

If you agree to let the patient join this study, the researcher will look at the patient's personal health information and collect only the information that is needed for the study. Personal health information is any information that could identify the patient and includes his/her:

- name,
- address,
- gender,
- date of birth, [month, year],
- Pittsburgh Agitation Scale and the notes of the patient's behavior recorded from the nurses during each shift.

Any personal information related to the patient (information about him/her that identifies him/her as an individual) collected or obtained, whether he/she chooses to participate or not, will be kept confidential and protected to the extent permitted by applicable laws. All personal information collected will be kept securely with access restricted to the research team. The study staff and the University Health Network Research Ethics Board (UHN REB) will have access to his/her personal information for purposes associated with the study, but will only be allowed to access his/her records

under the supervision of the Principal Investigator xxx and will be obligated to protect his/her privacy and not disclose his/her personal information.

Electronic data will reside in a password protected folder and securely stored on the UHN servers. The computer that will be used to temporarily store the data will be encrypted and password protected to prevent any data breach or loss. All the data will be transferred to the UHN servers, which are encrypted and secure, for data analysis and long-term data storage. In addition, a copy of the pressure mat data will be stored in a BAMLab secure server. The BAMLab is the company where we purchased the pressure mat. The data needs to be stored on their server to prevent possible missing and lost data. The pressure mat data will be de-identified data and will not include any of the personal information. All data files will be kept strictly confidential within the research team and will not be shared with others without your express permission.

When the results of this study are published, the patient's identity will not be disclosed. All identifying information, such as faces, tattoos and scars, will be de-identified in any presentation and/or publication of the results. The patient will not be named in any reports, publications, or presentations that may come from this study.

Recorded data from non-participated [sic] patients will be kept strictly confidential and will not be used for any purposes. Only the research team will have the access to it. These data will not be included in the research study and will not be shared outside the research team in any way.

The data for this study will be retained for five years after the date of study closure. All data will be destroyed five years after the date of study closure.

Voluntary Participation

The participation in this study is voluntary. You may decide for the patient not to be in this study, or may decide for him or her to be in the study now and then change your mind later. The patient you are responsible for may leave the study at any time without affecting his/her future medical treatment, provision of health [sic], or his/her current or future residential status at the unit. We will give you new information that is learned during the study that might affect your decision of whether to let the patient stay in the study.

Withdrawal from Study

The unit allied health workers will watch out [sic] any verbal and non-verbal signs indicating dissent for study participation from patients during his/her involvement of the study. The researcher will contact you if any dissent identified from the patient. If the patient decides or you decide on behalf of him/her to withdraw from the study during the middle of the study, one of the researchers will remove the sensors installed in the patient's room and their wristband. With input from the patient, you will be the one to formally withdraw the patient if he/she does not want continue to be involved in the study.

If you decide to withdraw the patient from the study, you have the right to request withdrawal of information collected about him/her. Should you choose to let him/her withdraw from the study you are encouraged to contact Research Manager xxx at xxx or email xxx immediately.

If he/she leaves the study, the information that was collected before he/she left the study will still be used in order to help answer the research question. No new information will be collected without your permission.

Costs and Reimbursement

There are no costs to participate in this study.

There is no monetary compensation or reimbursements for participation in this study.

Rights as a Participant

By signing this form the patient does not give up any of his/her legal rights against the investigators, sponsor or involved institutions for compensation, nor does this form relieve the investigators, sponsor or involved institutions of their legal and professional responsibilities.

Conflict of Interest

Researchers have an interest in completing this study. Their interests should not influence your decision of whether to let the person with dementia participate in this study.

Commercialization

Should this research result in commercialization, UHN researchers intend to claim sole ownership of any results that would come from this study. You and the person you are responsible for will not receive any financial benefit that might come from the results of this study.

Incidental Finding

We are using video cameras to record patient's life on the unit. If any abusive behaviors towards patients are captured from the video recordings, the researchers will consult it [sic] with an independent third party, xxx, Professional Practice Chief for Occupational Therapy at xx Health Sciences. xxx will provide guidance in distinguishing between reportable events and unreportable events to REB and the Geriatric Psychiatric Unit. In case of reportable events, the researchers will report the incident to UHN REB via the unanticipated problems form. You will also be informed of the incident by the Geriatric Psychiatric Unit.

Questions about the Study

If you have any questions, concerns or would like to speak to the study team for any reason, please contact Research Manager at xxx or email xxx

If you have any questions about the rights of the person with dementia you are responsible for as a research participant or have concerns about this study, call the Chair of the UHN REB or the Research Ethics office number at xxx. The REB is a group of people who oversee the ethical conduct of research studies. The UHN REB is not part of the study team. Everything that you discuss will be kept confidential.

You will be given a signed copy of this consent form.

Consent

This study has been explained to me and any questions I had have been answered.

I know that I may let the person with dementia leave the study at any time. I agree to the use of the information from the person with dementia as described in this form. I agree to let the person with dementia take part in this study.

In addition, I also agree for any photograph/video of the patient to be used for (check all that apply):

☐ Other research studies on the same topic

☐ Teaching and demonstration at the University of Toronto

☐ Teaching and demonstration outside the University of Toronto

☐ Not to be used for any purpose other than this research study

In agreeing to the use of his/her photograph/video for the above purposes, I understand that the identity of the patient will be made secret by blocking out his/her face and any other distinguishing features. I also have the right to withdraw my permission at any time.

Name of person who will be taking part in the study:

_____

Print name of substitute decision maker (SDM)	Date	Signature

My signature means that I have explained the study to the participant named above. I have answered all questions.

Print name of person who obtained consent	Date	Signature

Was the substitute decision maker (SDM) assisted during the consent process? ☐ YES ☐ NO

If **YES**, please check the relevant box and complete the signature space below:

☐ The person signing below acted as an interpreter for the SDM during the consent process and attests that the study as set out in this form was accurately interpreted and has had any questions answered.

_____ _____ _____

Print Name of Interpreter Signature Date

_____

Language

Non-consent

The study has been explained to me and I decline to participate in full. In particular:

2) ☐ I do not want recordings of him/her in the common areas to be included in this research study. The researchers will not analyze video data related to him/her.

Recording Notice

You may be videotaped in some areas of the Geriatric Psychiatric Unit

Please note that some areas of the Geriatric Psychiatric Unit are being video recorded for **research purposes**. The study is been [sic] conducted by Toronto Rehabilitation Institute.

Why we are recording: the study is to look at some factors that cause agitation or aggression in persons with dementia who are currently residing in the unit. The purpose of the cameras is to record period of agitation to be used to identify factors that precede these behaviours. This research will be used to develop a system that can predict the occurrence of these behaviors in the future.

Locations of recording: the recorded areas are the hallways, dining/activity room, and patient lounge room.

All video that we captured will be kept secure and confidential. Your video recordings may be viewed by researchers if you have interactions with patients who are participating in the study.

If you DO NOT want your recordings to be viewed or have any questions or concerns, please contact xxx via email xxx or phone xxx.

Thank you!

[Posting date]

[Name of researcher]