Living lab smartQare, Sensire and NAAST

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Primary objective 1) To evaluate the usability of the total viQtor solution applied and used 24/7 in clinical practice.This includes the ease of use and/or usability of:the wearable, charger and armband by the primary participants/usersthe *care...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON51351

Source
ToetsingOnline

Brief title
LL

Condition

- Other condition

Synonym
Not applicable

Health condition

Het betreft het monitoren van de gezondsheidstoestand bij kwetsbare ouderen met 1 of meer chronische aandoeningen en/of een verhoogd valrisico

Research involving
Human

Sponsors and support

Primary sponsor: smartQare B.V.
Source(s) of monetary or material Support: Het onderzoek wordt gedaan voor eigen

rekening en risico van alle betrokken onderzoekspartners,NAAST B.V. (medisch service center),smartQare B.V.

Intervention

Keyword: Chronical diseases, Homecare, Vital signs, Vulnerable elderly

Outcome measures

Primary outcome

1. The wearing comfort and ease of use of the viQtor (wearable) and the armband

for the users (qualitative feedback of users as well as the Net Promotor Score

- NPS).

2. The ease of use and usability of the app and the portal for the various

users (qualitative feedback of users as well as the Net Promotor Score - NPS).

Secondary outcome

N.a.

Study description

Background summary

Due to the aging population in the Netherlands, the group of people of 65+ will grow very quickly in the coming decade. The share of people with an age over 65 in the Netherlands is expected to increase from 18.5% in 2017 to almost 24% in 2030, an increase of more than 1 million elderly people. In 2030, there will be 26% more people with an age of 75+ than today (Van Duin & Stoeldraijer, 2017) (CBS, 2014). In contrast, the working population will decrease in absolute numbers. Currently, 1 out of 7 people in the Dutch workforce works in healthcare. Given the growing demand for care, without any actions, this will need to increase to 1 out of 4 people by 2040 (Van Duin & Stoeldraijer, 2017) (CBS, 2014).

Healthcare needs innovative solutions to be able to continue to guarantee quality, affordability and accessibility of care, in a situation where the shortage of personnel is increasing (125,000 vacancies in elderly care are expected by the end of 2022) and the demand for care will only increase due to

an aging population (Vermeeren, 2019).

Most elderly people wish to stay at home as long as possible, but often physical disabilities and cognitive impairment make this difficult (Roy et al., 2018). Dutch government policy focuses on supporting elderly people to continue to live their life independently at home as long as possible (Ministerie van Algemene Zaken, 2021). Given the vulnerability of this population, it is important to monitor their well-being, while living independently, in order to prevent deterioration of health conditions. In the Netherlands in 2020, per day 14 people died as a consequence of a fall, of which 12 were elderly people (Letsel Informatie Systeem 2011- 2020, VeiligheidNL; Bevolkingsstatistiek 2011-2020, Centraal Bureau voor de Statistiek; Doodsoorzakenstatistiek 2019, Centraal Bureau voor de Statistiek). Often, these deaths were the result of a deterioration of the health condition, due to the fact that the fall remained unnoticed and people were laying on the floor for a long period of time.

Continuous monitoring of vital signs using wearable devices has been found to allow for early detection of clinical health deterioration in intensive care units (Leenen et al., 2020). There is a growing interest in using remotely continuous monitoring as a common practice with the objective to allow timely intervention from health professionals (Askarian et al., 2019 & Pataranutaporn et al., 2019). These findings may be transferable to the homecare setting, but have not been sufficiently investigated yet. Moreover, with progress in medicine and healthcare systems, the average life expectancy of human beings has increased to more than 80 years of age, which results in more falls among the elderly population (Ramachandran & Karuppiah, 2020). The health consequences of a serious fall have a great impact on someone's mood and independence and can even result in death (Kannus et al., 2015). The effect of using continuous fall detection for elderly people in a home setting has yet to be established, but could possibly contribute to a more confident, independent and longer life.

The viQtor solution can play an important role in remote monitoring of people living at home. The viQtor solution consists of a medical wearable (viQtor), to be worn in an armband around the upper arm and a cloud platform (monitoring system). viQtor continuously (24/7) measures skin temperature, heart rate, oxygen saturation and activity. The system transfers these measurements every five minutes to the cloud platform (via the narrow band internet of things). viQtor also contains fall detection and a personal help button. In case of a detected fall, the activation of the help button or a deviating measurement of a vital function, the solution transmits an alert and the location of the primary participant is also transmitted. Via the cloud platform the monitoring information is selectively shared with professional and informal caregivers. The viQtor solution is intended to monitor people with one or more chronic conditions (in particular COPD and heart failure patients) and/or an increased risk of falling, in order to early identify (and possibly predict) a deterioration of the health situation, so that timely action can be taken

and/or the treatment can be adjusted. viQtor is not meant for the monitoring of acute problems based on vital functions.

As the viQtor solution offers continuous remote monitoring of people*s health situation, it could possibly contribute to people*s quality of life and quality of care. Furthermore, based on literature research and analysis, in case of national implementation of the viQtor solution, the potential financial impact in the first year is a cost reduction between ¤730 and ¤830 million*. The rationale for this estimate can be found in attachment *C1c Business case viQtor solution*.

To further investigate the full potential of the viQtor solution, it is important to test the usability of the viQtor solution and to examine to what extent it fulfils its intended purpose in clinical practice.

Study objective

Primary objective
1) To evaluate the usability of the total viQtor solution applied and used 24/7 in clinical practice.
This includes the ease of use and/or usability of:
the wearable, charger and armband by the primary participants/users
the *care circle app* by the informal caregivers and the primary participants/users
the *healthcare professional app* by the healthcare professionals
the portal by the healthcare professionals
the portal by employees of the medical service centre

Study design

The study is a single arm usability mixed methods study in which 20 target users will test the viQtor solution for four weeks. From here on, they will be referred to as the *primary participants*of the study. The target users are all patients who receive homecare from Sensire The medical service centre, NAAST, will do the 24/7 monitoring of the primary participants via the monitoring portal. Healthcare professionals will get access to the health data of the primary participants via the portal and the app. Informal caregivers will get access to the app, to be involved in the care process and assist the primary participants in the use of the viQtor solution. Employees of medical service centre NAAST, healthcare professionals of Sensire and informal caregivers of the patients will be the secondary participants of this study.

During the study, primary participants will be asked to wear viQtor 24/7 for 4 weeks. Primary participants are asked to continue with their normal life while wearing viQtor. Additional actions for primary participants, associated to the participation in this usability study are: charging viQtor for 2 hours every

day, washing the viQtor armband every now and then and keeping a diary to note any noteworthy feedback regarding their experiences with viQtor. Primary participants will be asked to press the personal help button when they need help immediately, in addition to (and never instead of) their current personal alarm system, if applicable. The primary participants will be called, once every two days for 5 minutes, to check if they are experiencing any inconveniences and if everything is working according to its intended purpose.

The monitoring portal will be used 24/7 by employees of NAAST for the monitoring of primary participants. In case an alert is received by NAAST, due to the activation of the personal help button, the detection of a fall or an abnormality of measured vital functions, NAAST will contact the primary participant and will execute their existing protocol. In case needed, the care team of Sensire of the primary participant will be contacted to support the follow up, according to the existing protocols of NAAST and Sensire. NAAST will call the primary participants, once every two days for 5 minutes, to check if the primary participant is experiencing any inconveniences and if the viQtor solution is working according to its intended purpose.

At the end of the test period, primary participants, informal caregivers, healthcare professionals of Sensire and employees of the medical service centre, NAAST, are asked to complete a questionnaire or participate in an interview, regarding the ease of use and usability of the viQtor solution. The questionnaire for the primary participants will be administered in person.

The primary participant's existing home care remains unchanged. Where applicable, based on the measurements and alerts that are generated by the viQtor solution, additional checks of primary participants will be performed, according to an established protocol.

Study burden and risks

Burden:
The subjects are involved in the study in such a way that they will wear and test viQtor as much as possible for 4 weeks. They will not have to make any changes to their daily activities while testing viQtor. The care of the subject remains as contracted and additional checks may be performed on the subjects based on the measurements of viQtor. Existing care will not be adjusted based on viQtor's measurements.

The subjects will be interviewed during the course of the study regarding the wearing comfort and ease of use of viQtor and asked to keep a logbook if they notice any particulars regarding the use of viQtor. ViQtor will measure skin temperature, heart rate, oxygen saturation and activity during the wearing period and provide an alert if a subject should fall or press the personal help button. The test subject does not have to do or not do anything for these measurements.

Risks:
1. Subjects with extremely sensitive or fragile skin may experience minor skin irritation or minor skin damage as a result of wearing viQtor on the upper arm.

Consequence (1-5): 3
Probability (1- 5): 2
General risk (1-25): 6/25

Risk mitigation measures:
The viQtor carrying strap is adjustable and can be tightened to fit any arm. The following measures are taken to prevent minor skin irritation or minor damage to the skin:
A. Extremely sensitive skin is an exclusion criterion for participation
B. The researchers instruct the user, caregiver and healthcare professional to tighten the sling so that two fingers still fit between the sling and the arm.
C. The subjects will be regularly checked by healthcare professionals for negative effects / damage on the skin beyond the expected normal skin impression of viQtor and measures will be taken if necessary (possibly discontinuing participation).
D. Subjects are instructed to remove the strap immediately if they suspect skin damage.
E. The viQtor strap is designed with a medically approved fabric and with the aim of being as comfortable as possible for the wearer

2. Risks of bacteria and skin infections from wearing

Consequence (1-5): 3
Probability (1- 5): 2
General risk (1-25): 6/25

Risk mitigation measures:
A. viQtor has a smooth surface and the band is hyperallergenic.
B. The user information includes cleaning instructions for the device and for the sling.
C. The sling strap is easy to replace and washable.

3. The subjects of the participating care organization in the study (the intended users of the portable aid) mainly consist of elderly people (not in life-threatening situations) with care provided at home by the care organization. Due to the vulnerability of the intended users, it cannot be ruled out that life-threatening situations may arise during the investigation, with critical or fatal injuries as a possible outcome. The viQtor solution is not intended to detect acutely life-threatening situations in a timely manner - to the extent that such situations are detected, the urgency of such a measurement / notification has not been taken into account in the design and the timeliness of the becoming available these measured values **/ messages are

not made a statement and a guarantee is issued.

Consequence (1-5): 5
Probability (1- 5): 1
General risk (1-25): 5/25

Risk mitigation measures:
In the event of a life-threatening situation, the normal functioning of viQtor may not contribute (either positively or negatively) to addressing the user's situation. Although viQtor may not be able to make a positive contribution to the treatment of the life-threatening situation in such a situation, the use of viQtor will not worsen the situation. viQtor is a device that is not intended as a medical device in life-threatening situations. This is also included as such in user information.

From a risk/benefit perspective, smartQare (the device manufacturer) believes that there will be no negative impact of viQtor on the user, but in most situations will have a positive impact on the care provided and actions during and after situations where help and/or medical assistance is required, especially when compared to a situation where the wearer does not use a monitoring solution. There is no service associated with this study, but a healthcare professional from the healthcare center will periodically analyze the data 24/7 and perform an extra check on test subjects, if the received measurements give reason to do so.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Being an adult (age 18+)
- Receiving home care from Sensire
- Suffering from 1 or more chronic conditions (as defined by Centers for Disease Control and Prevention (2021): *conditions that last 6 months or more and require ongoing medical attention or limit activities of daily living or both* and/or a higher risk of falling.

Exclusion criteria

- Having a history of anxiety disorders
- Having severe cognitive impairments
- Being unable to independently charge viQtor once a day, put viQtor in or get viQtor out the armband or put viQtor on the upper arm or take it off
- Being in acute life-threatening conditions or receiving intensive/palliative care
- Not physically being able to press the help button on their upper arm
- Having cardiac implants
- Wearing viQtor for a long time on the upper arm can have negative consequences for the skin or having sensitive skin.
- Residing in a location where the ViQtor solution has no connection coverage.

Study design

Design

Study type: Observational non invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	07-06-2022
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Generic name:	viQtor solution (E-health solution including a medical wearable)
Registration:	No

Ethics review

Approved WMO

Date:	03-06-2022
Application type:	First submission
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL80088.000.22