USECARE

Study protocol
Deliverable 2

AAL PROGRAMME

ACTIVE AND ASSISTED LIVING PROGRAMME
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Deliverable identity

Workpackage No.	**WP1 and WP2**	Workpackage Title	**Specifications**
Deliverable number		**2**	
Deliverable title		**Study protocol**	
Workpackage involved		**WP1 Specifications** **WP2 Development** **WP3 Observations**	
Authors:		**Contribution from all partners**	
Status (D-draft; F-final):		**F**	
File Name:		**20170201_D2_Study_protocol.doc**	

Summary

This deliverable comprises the different elements developed to design the study protocol pulished at https://clinicaltrials.gov/ct2/show/NCT02832739. The objectives of the study protocol are (1) to test the usability from community-dwelling, chronically ill older adults' and informal caregivers' perspective in using the SENACA prototype in everyday life; (2) to analyse and map the SENACA prototype as a complex self-management intervention from a technological, educational and behavioural perspective using established frameworks and taxonomies and (3) to explore the evolution of outcome parameters (clinical, behavioural and quality of life) deemed to be responsive to the SENACA prototype over time from baseline until end of data collection. The deliverable is structured in seven sections. Section 1 addresses how behavioural economics is applied to the SENECA platform; Section 2 describes the research design in detail; Section 3 shows the usability tests conducted; Section 4 comprises data security (*confidentiality*, *integrity* and *availability*) risk assessment performed; Section 5 contains the Bibliography and Section 6 includes complementary materials as Annexes.

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1 Insights from Behavioural economics

1.1 Background

Despite of the fact that most health systems are moving towards a patient centric models, still there is a common understanding of patients as rationally self-interested agents who are sometimes ignorant or forgetful following a classical model from economic theory. This theory generally assumes that people solve important problems as economists would using the idealized "homo economicus" of traditional economics who is perfectly informed, forward-looking, invariant in his preferences, and whose decisions are unencumbered by irrelevant contextual influences (i.e., rational). Behavioral economic scholars have found very convincing evidence that people are different from the rational being, the *Homo Economicus*, which has been a popular idea for quite some time (Camerer, Loewenstein, & Rabin, 2004; Heukelom, 2007; Kahneman, 2003; Kahneman & Tversky, 1979; Tversky & Kahneman, 1983). People appear to make irrational choices about health behavior that are situation or context specific, in particular under uncertainty. This results in cognitive errors and failures to optimize health (Kahneman, 2012). In other words, people report that they want to be and remain healthy, but irrational decision-making based on false assumptions affects this negatively, and has detrimental effects for older adults (Westendorp & van Bodegom, 2015).

Behavioral economics typically uses and eclectically integrates insights from a great variety of disciplines (e.g. psychology, sociology, biology, neuroscience, economics), thereby trying to explain, via for example prospect theory (Kahneman &Tversky, 1979), how decisions are made (Kahneman, 2012). In addition, economic prospect theory promotes libertarian paternalism (Thaler & Sunstein, 2003) that tries to direct people subconsciously into the "right" direction. This has often been referred to as "nudging" (Leonard, 2008).

Prospect theory describes irrational choices in which people use a valuation function exhibiting loss aversion and diminishing sensitivity, whereby people use a weighting function that overweighs low probabilities and underweights higher probabilities, leading to behavior that is not in the "correct" direction (Kahneman, 2012). The prospect theory suggests that the value of a health outcome is not an absolute number but rather a relative one, compared to one's current health-status. Every individual has an initial condition for assessment, or reference level, that represents the current health-related wealth (Treadwell & Lenert, 1999). Changes in health are valued not according to absolute qualities, but rather according to whether they are increments or decrements relative to the reference level. Relative increments are called gains, and relative decrements are called losses.

In this context, the term "**bounded rationality**" has been coined to describe the limited information-processing capabilities of real humans, as opposed to the *Homo Economicus.* Due to these limitations, individuals adopt **rules of thumb or mental shortcuts (heuristics)** within their decision-making process. Although such heuristics generally are useful, they also can lead to severe and **systematic errors or biases** that cause unhealthy behavior. (Mullainathan & Thaler, 2000; Tversky & Kahneman, 1974). In addition to this term, two other concepts have reflected constrains faced by the "rational individuals": bounded willpower and bounded Selfishness.

The **concept of bounded willpower** reflects the fact that people do not always make choices that are in their best long-term interest, due to a lack of self-control. These problems arise in

situations involving inter-temporal choice when the costs and benefits of a decision are separated across time. This is the case of the majority of preventive behaviors, as the costs of the behavior are separated in time from the benefits that occur at some time in the future or the other way around, the fun is now (enjoying a cigarette), whereas the costs come later (sinful goods). Three examples of constructs used by behavioral economists that relate to bounded willpower are: feedback, commitment contracts, and channel factors (Thorgeirsson & Kawachi, 2013).

The **concept of bounded selfishness** consists of relaxing the assumption that actors are motivated by "pure" self-interest. Behavioral economics models also are based on self-interest but modify and extend this concept to include altruistic and spiteful behaviour (Simon, 1993) supporting peer-based interventions.

In the upcoming paragraphs it is outlined how behavioral economics is able to explain irrational decision making in health related behavior among older adults. In addition, how SENECA could overcome these irrational decision-making is explained by following libertarian paternalism principles that could be conducted to successfully reduce unhealthy behavior and promote healthy behavior among older adults. SENECA should make use of these principles to direct older adults in the correct direction; in other words, to nudge them. Behavioral economics states that there are three prevalent themes that are related to irrational behavior and could be used to adapt health behavior positively (Westendorp & van Bodegom, 2015): Heuristics, Framing and Mispricing and non-rational decision making.

1.2 Heuristics and biases

First, behavioral economics showed that heuristics are important in decision-making (Kahneman, 2012). Mostly people make decisions based on approximate rules of thumb, and do not use strict logic or knowledge about or experience with statistics to make their decision, even if the information is available. The most common example is smoking. People smoke and know that it increases the possibility to get lung cancer. In particular, people have become more aware of this due to the labelling of the package, although the effectiveness of such an intervention is limited and more effective in communicating the health risks of smoking if warnings contain graphic, large, and more comprehensive in content (Hammond, Fong, McNeill, Borland, & Cummings, 2006). By means of cognitive-dissonance reduction, smokers are more likely to hold pessimistic cancer beliefs than never-smokers or former-smokers (Quaife, McEwen, Janes, & Wardle, 2015). Many major health problems, such as lung cancer, hypertension, and diabetes, are exacerbated by unhealthy behaviors that could have been reduced if people used the correct risk perceptions and act accordingly (Loewenstein, Brennan, & Volpp, 2007) as people form their own risk perceptions by heuristics instead of using factual knowledge, and do not become motivated to move in the correct direction. The following are examples of heuristics.

- **Anchoring**. The anchoring effect, first discussed by Tversky and Kahneman (A. Tversky & Kahneman, 1974), occurs when a prior belief exerts an influence on the way new information is processed and new beliefs are formed, even when such prior has no logical relevance for the issue at hand
- **Availability**. Another heuristic is "availability" –i.e. judging frequency by how easy certain events or outcomes come to mind (A. Tversky & Kahneman, 1974). Imagine to be asked to judge the likelihood of the combination of 2 individuals taken from a group of eight, as

compared with combination of six individuals. Since any group of 2 would generate a group of six, it is easy to determine that they are equally likely; but it is easier to compute mentally the combination of two and for this reason individuals tend to judge the first one as more likely. Another typical bias induced by this heuristic is illusory correlation, in which data are thought to be associated because they are easy to retrieve, but no underlying causality is exists.

- **Representativeness**. This is a heuristic in which the likelihood of an event is determined on the base of the similarity to a certain set of data. This heuristic induces a series of biases: e.g. assessment of the likelihood of the results is done without taking into consideration the dimension of the sample. By extension this bias, as anticipated, is also considered at work when individuals judge the value of an object based only on its appearance.

Heuristics are not necessarily bad, since they are "procedurally rational": they are parsimonious way of facing uncertainty given limited cognitive and computational ability. However, they tend to induce biases (violation of basic statistical principle or logic). Below we report some selective and non-exhaustive examples of the more well-known and tested biases in alphabetical order.

- **Exposure**. The degree of exposure to information can affect final judgment. Features in a temporal sequence, such as duration of exposure, the spread of experiences, the partitioning of episodes, and the peak-and-end events have been reported to influence a person's overall impression of the experience (Varey & Kahneman, 1992).
- **Gambling fallacy/small numbers**. Another typical example is the gambling fallacy, where people reason on small samples applying the law of large numbers: tossing a coin, experimental subject consider a certain outcome more likely if it has not occurred in a small set of trials, even if outcomes are equally likely as the coin has no 'memory'.
- **Order**. Order effect refers to the way in which the temporal order that information is presented affects a final judgment and can be subdivided into the primacy and recency effects (Luchins, 1957; Wang, Zhang, & Johnson). With primacy, an individual's impressions are more influenced by earlier information in a sequence; with recency, impressions are more influenced by later information.
- **Reinforcement**. Repeated exposure to information may influence the way beliefs are formed. Zajonc (1968) found that there was a linear log relationship between the frequency with which a subject was exposed to a stimulus and the subject's enhanced attitude towards the stimulus, regardless of whether the stimulus was a nonsense word, a symbol or a photograph of people.
- **Self-serving bias**. This is the tendency to claim more responsibility for successes than failures. It may also manifest itself as a tendency for people to evaluate ambiguous information in a way beneficial to their interests.
- **Status quo bias**. It refers to the irrational preference for the current state of affairs. The current baseline (or status quo) is taken as a reference point, and people evaluate changes from that baseline in terms of gains and losses (D. Kahneman, Knetsch, & Thaler, 1991).
- **Valence**. The valence effect of prediction is the tendency for people to simply overestimate the likelihood of good things happening rather than bad things. Valence

refers to the positive or negative emotional charge something has. This finding has been corroborated by dozens of studies. In one straightforward experiment, all other things being equal, participants assigned a higher probability to picking a card that had a smiling face on its reverse side than one that had a frowning face. In addition, some have reported a valence effect in attribution when we over-predict the likelihood of positive events happening to ourselves relative to others. (related to self-serving bias.). The outcome of valence effects may be called wishful thinking. However, in certain situations, the valence effect may actually alter the event in some way so that it indeed results in a positive outcome. For example, in some cases generals have roused up their soldiers to a point where they were able to emerge victorious in battle.

1.3 Framing

Second, behavioral economics states that framing is an important aspect of explaining and predicting how people make decisions, also with regard to their health (Kahneman, 2012). For example in eating behavior, framing has been repeatedly shown to be an important factor that affects when, how, and what we eat (Chandon & Wansink, 2012). Food decisions are made with little cognitive involvement and food policies designed to appeal to highly cognitive thought (e.g., fat taxes, detailed information labels) are likely to have little impact (Chandon & Wansink, 2012). Given the limited cognitive ability of individuals to retain and use accurate health information coupled with varying levels of self -control, profit motivations of marketers can become predatory--though not necessarily malicious. Alternative policy options that do not restrict choice are outlined, which enable consumers to make better decisions. These options allow for profit motivations of marketers to align with the long-term well-being of the consumer.

A review analyses (Gallagher & Updegraff, 2012) showed that gain-framed messages appear to be more effective than loss-framed messages in promoting prevention behaviors. Research should examine the contexts in which loss-framed messages are most effective, and the processes that mediate the effects of framing on behavior. In contrast, a systematic review by Cochrane Institute (Akl et al., 2011) showed that contrary to commonly held beliefs, the available low to moderate quality evidence suggests that both attribute and goal framing may have little if any consistent effect on health consumers' behavior. The unexplained heterogeneity between studies suggests the possibility of a framing effect under specific conditions. Future research needs to investigate these conditions.

One example of health related behavior where a robust framing effect is found is food intake. It was found repeatedly that people not only eat more if food was served on a larger plate, but they also reported, after being shown the results, that this was an exceptional case and portion size normally does not affect them without hem knowing (Wansink, 2014; Wansink & Cheney, 2005). Framing food intake differently by using larger or smaller plates influences food intake, while hunger levels were the same, and people afterwards reported that it did not influence their food intake.

1.4 Mispricing and non-rational decision making

Third, mispricing and non-rational decision making is an important factor of how health behavior is negatively affected. In some cases, individuals lack information, but in others, they just seem to act contrary to their own known interests, in particular, when they overeat, fail to

take medication, or neglect to wear seat belts (Loewenstein, Volpp, & Asch, 2012). For example, many studies show that people avoid to see doctors or do not conduct tests because of anxiety and fear of receiving negative results, even though this may prevent the disease onset or enable better diagnosis and cure (Fels, 2012; Kőszegi, 2003; Kőszegi, 2006; Kőszegi & Rabin, 2006; Panidi, 2008). In addition, patients conduct non-rational decision making in the intake of medicines, which is detrimental for their health. For example, when taken properly the drug warfarin, it reduce the risk of strokes by 65% overall and by 85% in individuals older than 75 with a least on risk factor, while a cohort study showed that 40% of subjects missed 20% or more of their warfarin doses, thereby significantly reducing their health status (Lowestein, John, & Volpp, 2013).

Furthermore, the health sector is also characterized by institutions and decision making circumstances that, in addition to making cognitive errors more likely, create friction that impedes market adjustments that might lead to correction of errors over time (Cutler, Glaeser, & Shapiro, 2003; King, Mullinathan, Shafir, Vermeulen, & Wrobel, 2011). These include the stress of decision making about one's health, professionalism, and a lack of information about medical care, which in return influence patients decisions to withdraw from patient-doctor relationship.

1.5 SENECA approach

SENECA does not has this same problem because it shows immediately the health risks of one's current situation, based on scientific research, and suggests alternative behavior to reduce this risk, thereby motivating people to live healthier. SENECA is able to overcome the cognitive biases described above successfully by directing people and support health promoting behaviors, via libertarian paternalism ("nudging"). For example, both government and businesses in the UK and the Netherlands have embraced nudge approaches to healthcare (Bonell, McKee, Fletcher, Haines, et al., 2011; Bonell, McKee, Fletcher, Wilkinson, et al., 2011; Marteau et al., 2011; Westendorp & van Bodegom, 2015). Below it is summarized what libertarian paternalisms is and how SENECA can use the suggested implementations to successfully help older adults to live healthier.

Libertarian paternalism is the influence of an agent or organization of a choice, of some other people, to move them into the "right" direction (Thaler & Sunstein, 2003). Libertarian paternalism refers to certain adaptations or policies, thereby only limited interfering with people, to help people who behave irrationally and in this way are not helping their own interests, to get more in the direction they want to be. The false assumptions of economists, and laymen, regarding paternalism, that it is an oxymoron, lies in the fact that people are always making choices in their best interest and that paternalism always involves coercion. The SENECA-program could be such an agent or organization that influences the choice of others in the self-directed "right" direction. In the SENECA-program, people are free to choose to participate and to drop out, they are only instructed how they can influence their own choices and monitor or keep track of their own health behavior. This will promote their health behavior in certain ways and the locus of control of their behavior will be perceived as self-directed behavior.

The basic idea behind the nudging-plan is that people procrastinate and have bounded rationality (Findley & Caliendo, 2010; Kahneman, 2012: Thaler & Benartzi, 2004; Thaler & Sunstein, 2003). Procrastination is to defer tasks to a later time with counterproductive

consequences (Reuben, Sapienza, & Zingales, 2007). Factors that relate to procrastination are impatience, uncertainty and utility from memory. If people have to choose between doing a task now or a somewhat larger task later in time, they would choose the latter. People are weighing current and near-term consumption especially heavily, in contrast to long-term consumption and effort. For example, many people are paying for not going to the gym (DellaVigna & Malmendier, 2006), while multiple studies (Jeon, Lokken, et al., 2007; Seals, Kaplon, Gioscia-Ryan, & LaRocca, 2014; Lee, I-Min, et al., 2012; Woodcock, Franco, Orsini, & Roberts, 2011) have shown that physical activity and diet exert a strong influence on endothelial function with aging, risk of coronary heart disease, breast cancer, and all-cause mortality. Problematic is that lifestyle-based strategies are limited by low adherence in most human populations (Seals, Kaplon, Gioscia-Ryan, & LaRocca, 2014). Continued advocacy for broad engagement in these healthy behaviors is essential, because these approaches will have the greatest impact on endothelial function, as well as numerous other (nonvascular) physiological declines with aging. Consumers are often unable to compute the optimal health plan, and so they follow a rule of thumb which in principle leads to unhealthy behaviors (Findley & Caliendo, 2010).

In this scenario, libertarian paternalism emphasizes the possibility that in this case individuals make inferior choices, choices that people would change if they had complete information, unlimited cognitive abilities, and no lack of willpower (Thaler & Sunstein, 2003;Vohs, Baumeister, & Schmeichel, 2012). SENECA could be very effective for increasing health related behaviors among elderly by nudging them towards a more healthy life-style. For example, the above mentioned studies showed that people use heuristics for risk perception in health behavior instead of factual knowledge. SENECA could overcome this by providing people up-to-date risk estimations in a simple form, whereby they clearly should show the losses and gains of personal developments in health related behavior. This may help people to adapt their health behavior in a more positive direction by providing personal factual knowledge to increase healthy behavior and to reduce the health risks. Examples of this could be to online text messages (e.g., telephone, watch, tablet) that makes older adults more aware of the (dis)advantages of being active, quality of sleep, and eating behavior, by giving the exact numbers of risk estimates on different (chronic) diseases, based on their current situation, that could be reduced if they become more active (Foulds, Bredin, Charlesworth, Ivey, & Warburton, 2014).

Next, it seems that people are subconsciously affected by environmental factors that frame health behavior, of which they are not yet aware. Making them aware of these influences could increase conscious control over these mechanisms, for example to decide to use smaller plates before one starts eating or longer and smaller glasses when drinking soda (Wansink, 2014; Wansink & Cheney, 2005), or other small changes in every-day life that increases physical activity (Westendorp & van Bodegom, 2015); all to promote healthy behaviors and to decrease risk for (chronic) diseases.

2 Research design

2.1 Background

Lifestyle-related non-communicable chronic diseases (NCDs) such as heart disease, respiratory disease or diabetes are considered a major challenge for healthcare systems in western societies (WHO, 2011; Rosenbaum & Lamas, 2011; IOM, 2012). These chronic conditions are accompanied by problems and unmet needs for community-dwelling older adults (Desai, Lentzner & Weeks, 2001) They include difficulties in accessing care and health-related information and lack of care coordination (Schoen, Osborn, How, Doty & Peugh, 2009). Monitoring and managing symptoms, medication and co-morbidities can also be challenging for older adults with chronic conditions and they may have to cope with social isolation, diminishing autonomy and independence as well as mental health problems (Wajnberg, Ornstein, Zhang, Smith & Soriano, 2013; Thorne & Paterson, 2000). All these challenges can add up to a serious symptom burden and affect their quality of life (IOM, 2012).
In their chronic disease self-management, community-dwelling older adults are often supported by family members, friends and/or neighbours as informal caregivers. They provide unpaid care on a daily basis including e.g. assistance and support in decision-making, activities of daily living, medication administration, wound care or communication with healthcare professionals (NAC & AARP Public Policy Institute, 2015; Given, Given & Sherwood, 2011; Liddy, Blazkho & Mill, 2014; Grey, Knafl & McCorkle, 2006). These informal care responsibilities may result in caregiver burden including emotional stress, financial constraints, long-distance caregiving or challenges in reconciling employment and elderly care, which can have negative consequences in terms of health and quality of life (NAC & AARP Public Policy Institute, 2015; Feil, Lukman, Simon, Walston & Vickrey, 2011; Cora, Partinico, Munafo & Palomba, 2012; Cagle & Munn, 2012; Janevic, Rosland, Wiitala, Connell & Piette, 2012).

Information and communication technologies (ICT) and chronic disease management

The previously mentioned risks and challenges of chronic conditions can be addressed by ICT-supported self-management interventions using various delivery modes (automated functions for e.g. information delivery or symptom monitoring, communicative functions for access to (peer-to-peer) advice or supplementary modes like email, telephone or short messages) (Webb , Joseph, Yardley, Michie, 2010). ICT-based interventions are considered relevant for educating and empowering people living with chronic disease (17,18). If well-designed meaning that interventions included are effective and developed on a user-centred design, such interventions can have a true added value for chronic disease management. The cost effectiveness is a factor that needs also to be tested in addition to clinical effectiveness. If proven to be effective and user-friendly for end-users also including healthcare professionals, they have a potential for scalability and may reduce healthcare spending while improving access to care, patient outcomes and quality of life (Oldenburg, Taylor, O'Neil, Cocker & Cameron, 2015; Stellefson, Alber, Wang, Eddy , Chaney & Chaney, 2015; Gaikwad & Warren, 2009).

Based on the current evidence, ICT-based healthcare interventions have small to moderate effects on health-related behaviour of chronically ill older adults and the potential to improve their quality of life (Eland-de Kok, van Os-Medendorp, Vergouwe-Meijer, Bruijnzeel-Koomen

& Ros, 2011; Macea, Gajos, Daglia Calil & Fregni, 2010; Hamine, Gerth-Guyette, Faulx, Green & Ginsburg, 2015). Webb et al. (2010) found that, on average, interventions using the internet to promote behaviour change had a statistically small but significant effect on health-related behaviour (d(+) = 0.16, 95% CI 0.09 to 0.23). Several benefits of ICT-based interventions for people living with chronic conditions have been reported, such as a significant positive effect on knowledge (SMD 0.46; 95% confidence interval (CI) 0.22 to 0.69), social support (SMD 0.35; 95% CI 0.18 to 0.52) and clinical outcomes (SMD 0.18; 95% CI 0.01 to 0.35) (23). A significant positive effect on continuous behavioural outcomes (SMD0.20; 95%CI 0.01 to 0.40) has also been found (ibid.).

Usability – technology acceptance by older adults

Various factors have been identified that may influence the acceptance, (non-)usage and adherence to ICT-based healthcare interventions by community-dwelling older adults and their informal caregivers (Peek et al., 2014). *Personality-based, social and clinical characteristics* may positively or negatively affect the ICT-use of older adults, in particular their familiarity with modern electronic technology, age or socio-economic status (Walczuch, Lemmink & Streukens, 2007)[1]. For instance, one study identified regular users of a web portal for patients living with type 1 and 2 diabetes mellitus as higher educated and younger than non-users (Ronda, Dijkhorst-Oei & Rutten, 2014). However, other studies found no age-, gender- or gravity-of-disease-related determinants of adherence to ICT-based interventions with a general higher acceptance amongst more self-determined patients and those with a desire to age in place, meaning to live independently at home for as long as possible (Peek et al., 2014; Prescher et al., 2014; Feil, Glasgow, Boles & McKay, 2000). Whether or not eHealth interventions are used by community-dwelling older adults also depends on their *concerns regarding technology*, for instance related to high cost, privacy or security implications (Stevenson, Lloyd, Harrington & Wallace , 2013; Pyper, Amery, Watson & Crook, 2004). In addition, personality traits of individuals such as optimism, innovativeness, discomfort and insecurity play a significant role in predicting technology acceptance (Walczuch et al., 2007; Lam, Chiang & Parasuraman, 2008).

The success of ICT-based healthcare interventions also depends on whether intended users find them useful (Peek et al., 2014; De Vito Dabbs et al., 2009). *Usability* is defined as the measure of the ease with which a system can be learned and used, including its safety, effectiveness and efficiency (Preece et al., 1994). In terms of the usability of ICT-based healthcare interventions, older adults express e.g. problems related to functionality and practicability (poor design, navigation or unmet expectations), physical challenges to using eHealth and tele-monitoring solutions, low ease of use or lack of perceived benefit including poor integration with daily routines (Oldenburg et al., 2015; Ronda et al., 2014; Greenhalgh,

[1] Recent findings on digital health literacy in Europe indicate that more and more Europeans tend to use the Internet and online resources to manage their health. Yet, it also indicates a digital divide with a substantial group of Europeans having no or little access to online resources. Amongst those citizens open to the Internet and use of ICT, the majority (59% of 26'566 respondents in the Flash Eurobarometer 404) goes online to search for health-related information; of those who do, 63% are in good state of health compared to only 37% of Europeans in a poor state of health (57). Similar findings exist in North America, even though there, six out of ten older adults aged 65 plus go online daily (35) whereas currently about one third of Europeans aged 55 years or older use the Internet every day (57). On both continents, two sets of user groups amongst older adults have been identified: those with relatively substantial technology assets (younger, highly educated, better income and health status) compared to those largely disconnected (older, less affluent, significant health challenges or disability) (ibid.).

Hinder, Stramer, Bratan & Russell, 2010; Smith, 2014; Nijland, van Gemert-Pijnen, Kelders, Brandenburg & Seydel ER, 2011; Jimison et al., 2008).

If eHealth interventions do not align closely with end-users attitudes, self-management practices and information needs, there can be a substantial risk that they will not be adopted or adhered nor be sustainable over time as users stop using the technology (Greenhalgh et al., 2010; Jimison et al., 2008). Expectations and opinions towards ICT-based chronic disease management solutions may also change when older adults actively use them and, thus, may fluctuate over time (Peek et al., 2014 ; Ronda et al., 2014). A user centred design in ICT development is therefore the state of the art to guarantee a successful use and implementation in different contexts. Optimally, usability needs to be established before testing the effectiveness and will be an important driver in future scalability of ICT solutions (De Vito Dabbs et al., 2009).

SENACA – from web platform to self-management support system for older adults and informal caregivers

In Switzerland, an ICT-supported intervention consisting of a web platform for active health promotion and disease prevention for older adults has been developed including standardised tools for calculating chronic disease risk and evidence-based health information to increase health literacy. The development of this senior health academy (SENACA, www.senaca.ch) was originally funded by the Swiss State Secretary for Education, Research and Innovation and conducted in close collaboration with health professionals, behavioural scientists and ICT experts. Run by an independent SME (small and medium-sized enterprise) it has now evolved to the SENACA platform. It is a structured self-management support system and complex intervention with several interacting components (Craig et al., 2008), combining tele-monitoring devices and a solution for personalised health plans. In 2014, a limited feasibility pilot of the SENACA prototype has been conducted demonstrating its technological readiness for further testing and implementation[2]. In addition, selected clients of a major Swiss pharmacy and health service provider have used the prototype. Their feedback suggests that it may have added value for chronic disease management and risk prevention.

SENACA's *usability*, the *behaviour change techniques* it builds on, *modes of delivery* and its *effects on health-related behaviour, clinical and QOL outcomes* need to be established in a larger group of end-users. Testing the usability of SENACA and practical effectiveness of this complex intervention is the goal of the multi-national EU-funded ambient assisted living (AAL) project USECARE[3]. A consortium of three countries (Israel, Norway and Switzerland) will implement the enhanced SENACA prototype and will run a field test with older community-dwelling adults living with chronic conditions (i.e. diabetes, COPD, chronic heart failure) and informal caregivers. Findings from the study embedded in USECARE AAL will inform the prototype's future improvement and scalability process[4].

Key element of USECARE AAL is a multinational field-test of the enhanced SENACA prototype including a pilot-like study with two parts described in the following:

[2] Another feasibility round on the enhanced version of the SENACA prototype is scheduled for Spring 2016.

[3] For further information see www.usecare.eu for details (accessed April 2015).

[4] These include, for instance, an estimate of SENACA's macro-economic potential and the development of a sustainable business plan.

Part I – preliminary studies on usability of SENACA from the perspective of community-dwelling older adults as well as their informal caregivers (mixed methods) and on mapping the prototype's behaviour change components and intervention characteristics.

Part II – to explore outcomes of SENACA by using a **pre-experimental design** to observe the evolution of a number of parameters during the implementation period of the prototype.

2.1.1 Study objectives

By introducing the enhanced SENACA prototype to community-dwelling older adults with one or more chronic conditions as well as their informal caregivers, the **objectives** for the two pilot-like study parts are as follows:

Part I – Preliminary studies:

a. To test the usability from community-dwelling, chronically ill older adults' and informal caregivers' perspective in using the SENACA prototype in everyday life (including the evaluation of a number of process parameters related to the use of prototype)

b. To analyse and map the SENACA prototype as a complex self-management intervention from a technological, educational and behavioural perspective using established frameworks and taxonomies (e. g. Michie et al., 2013).

Part II – Pre-experimental design:

To explore the evolution of outcome parameters (clinical, behavioural and quality of life) deemed to be responsive to the SENACA prototype over time from baseline until end of data collection

Outcomes studied will be

as of **aim Ia preliminary studies (usability)**:

- usability (intention to use, perceived ease of use, perceived usefulness)
- technology experience, preference in using technology
- errors (number and type of technical problems occurring)
- user satisfaction (actual use of technology [one time baseline], relative frequency of module use of SENACA prototype, adherence to SENACA program: initiation, implementation, discontinuation [time to event])

as of **aim II pre-experimental design (evolution of outcome parameters)**:

- HbA1c, cholesterol, weight, BMI (clinical)
- physical activity, nutrition behaviour, smoking
- health-related quality of life (QoL)
- empowerment (e.g. self-efficacy and social support) and health behaviour process outcomes

The study findings and analyses combined will provide an insight into the end-user perception, usage patterns and potential added value of the enhanced SENACA prototype for chronic disease management and empowerment of community-dwelling older adults living with chronic conditions and informal caregivers. The findings will also help to identify how SENACA as a complex intervention works and what are its active ingredients. Insights from this study may fuel the development of estimates and calculations about SENACA's potential in decreasing burden of care and healthcare cost. Finally, exploring both acceptance and outcomes of SENACA may help to collect experiences on the research design and measurements used in the three countries, which may provide additional insight on how to test complex interventions like SENACA and be used as a stepping-stone for a potential future investigation on the effectiveness of the prototype.

2.2 Methods

2.2.1 Design

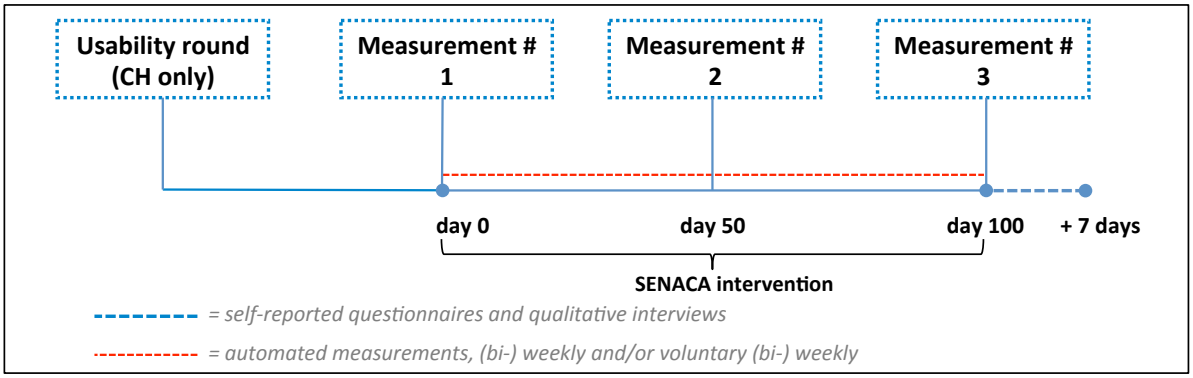
This multi-national and multi-centred mixed-methods study includes two parts:

I) **preliminary studies** on usability and analysis of the prototype from technological, educational and behavioural perspective (taxonomy-guided)

II) **the use of a pre-experimental design.** USECARE AAL is characterized by an existing complex intervention as well as funding for field-testing SENACA with a relatively small number of participants in three countries. Given the existing resources and limited timeframe of the project, there will be hardly any control over the sample formation as the USECARE AAL participants can neither be chosen by chance nor will they be representative of a certain population. However, the SENACA field-test is considered an opportunity for exploratory purposes on technology acceptance and various outcomes of the prototype. It is considered a cost-effective way to discern whether the potential exploratory findings are worthy of further investigation under more carefully controlled circumstances (Marquis, Larivée, Saey, Dubois & Tousignant, 2015). Thus, a pre-experimental design with a one-group pre-test post-test approach using a repeated post-test has been considered adequate for the exploratory purposes of USECARE AAL (Creswell, 2009; Campbell & Stanley, 1963; Shadish, Cook & Campbell, 2002). This design makes it possible to observe a number of parameters over time using repeated measures and mixed methods (QUAN-qual)[5] during the implementation of the enhanced SENACA prototype (Figure 1). This appears to be the way forward when researching in natural situations where there is a low level of control over context factors and the formation of sample, which both could affect the outcome. While being a reasonable research design for the USECARE AAL purpose, there will be clear limitations because of the pre-experimental character, i.e. that the internal and external validity is low, hypothesis testing is not possible and generalizing results should be avoided.

[5] The QUAN-qual model stands for an explanatory mixed methods design where quantitative data are collected first and are more heavily weighted (41).

Figure 1.USECARE AAL study design



2.2.2 Settings and sampling

Recruitment for the study takes place in healthcare organisations in the three participating countries – Israel (IL), Norway (NO) and Switzerland (CH) – where the SENACA prototype is implemented in private homes of community-dwelling older adults with chronic conditions. Members of the USECARE consortium along with affiliate healthcare organisations are involved for field access (predominantly healthcare providers like hospitals and / or out-patient clinics, see table 1 for details).

Table 1. Role of involved organizations in USECARE study

Organisation (in alphabetical order)	Role in study
Assuta Medical Center, Tel Aviv (IL)	Co-Investigator, Clinical Assessment
Institute of Nursing Science, University of Basel; Careum Research, Zurich (CH)	Investigator, Clinical Assessment
Joint Research Centre, Institute for Health and Consumer Protection, Behavioural Economics Team, Ispra (IT)	Analysis of Behavioural Economics
Medical Network EMN, Kilchberg (CH)	Provider of intervention (SENACA prototype)
Open University of Catalunia, Barcelona (ES)	Analysis of Behavioural Economics
University Hospital North Norway, Norwegian Centre for Integrated Care and Telemedicine, Tromsoe (NO)	Co-Investigator, Clinical Assessment
University Hospital Zurich, Department of Internal Medicine, Center of Competence Multimorbidity, Zurich (CH)	Co-Investigator, Clinical Assessment
University of Oslo, Dept. of Health Management and Health Economics, Oslo, Norway (NO)	Co-Investigator, Clinical Assessment

Participants

Participants in the study are community-dwelling older adults aged 50 years and older living with one or more chronic diseases who are at risk of developing complications and/or destabilization of their chronic conditions (primary end-users) and their informal caregivers (secondary end-users, i.e. spouses, children or other non-family and family members). Study participants are recruited from healthcare organizations in the countries participating in USECARE AAL. Table 2 lists the *inclusion and exclusion criteria*, which are straightforward:

Table 2. Inclusion and exclusion criteria for USECARE AAL study.

Community-dwelling older adults (primary end-users)	
Inclusion criteria	• receive medical care for one or more of the following chronic diseases in hospital settings and outpatient clinics: 1. Chronic Heart Failure (CHF, New York Heart Association NYHA II-IIIa); 2. Diabetes Mellitus (DM, 6< HbA1c<9), 3. Chronic Obstructive Pulmonary Disease (COPD, GOLD I-II) 4. Special Orthopaedic Co-Morbidity (SOCM, after elective hip or knee replacement, health status temporarily destabilized respectively challenged, increased monitoring and formal/informal care) • having support of an informal caregiver that is aged 18 years or older • are aged 50 years and older (community-dwelling older adults, primary end-user)
Exclusion criteria	• known illiteracy (reading and writing difficulties) • lack of local language proficiency • lack of internet access • current major mental illness of moderate to severe level • major acute illness or surgery in past 3 months (except elective hip / knee surgery for patients with SOCM) • participation in another intervention study
Informal caregivers (secondary end-users)	
Inclusion criteria	• aged 18 years or older • be named by primary end-user as designated informal caregiver providing physical, emotional and/or social support for him or her
Both older adults and informal caregivers	
Inclusion criteria	• written informed consent • adequate functional, sensory and cognitive abilities to use the SENACA system
Exclusion criteria	• does not have a stable address of residence • inability to handle ICT-devices due to cognitive or functional disabilities

Recruitment

After ethical approval of the study protocol in all participating countries, healthcare organizations collaborating with the consortium will provide access to eligible study participants. Principal respectively co-investigators will raise awareness and interest about USECARE AAL in collaborating healthcare organizations based on a study manual (including a refusal list), where clinicians (e.g. physicians and/or designated study nurses) will look-out for eligible participants. Written information material will be provided to inform eligible participants about the study during their regular visits at the respective healthcare organization. Clinicians will provide both oral and written information about the study (see annex 8) and the inclusion and exclusion criteria will be explained to the potential participants. If both the community-dwelling older adult and her/his designated informal caregiver are eligible and agree to participate, their contact data will be forwarded to national investigators of the USECARE consortium to provide additional information about the purpose of the trial, their rights, and possible benefits as well as risks of participation. They will also mail the informed consent sheet for formal willingness to participate (see annex 9) along with the baseline survey questionnaire (including items on socio-demographics, technology acceptance, and medical history).

2.2.3 Intervention

The enhanced SENACA prototype builds on a web platform originally developed for active health promotion and chronic disease risk prevention of older community-dwelling adults (www.senaca.ch). It has been enhanced by its developer to a *cloud-based structured self-management support system with tele-monitoring components* designed to be universally-interoperable with different medical devices, applications and web-based assessment instruments (see Figure 2). The enhanced SENACA prototype can be considered a complex intervention as it contains several interacting components and aims at a variability of behaviours of its users with a range of possible outcomes (Craig et al., 2008).

The enhanced SENACA prototype enables end-to-end wireless connectivity and allows end-users to access biometric data via mobile devices (tablets, smart phones) and personal computers by their choice. The enhanced SENACA prototype combines monitoring and behaviour change elements (under development) with access to evidence-based health information to address two end-user groups: older community-dwelling adults living with chronic conditions (primary end-users) and their designated informal caregivers (secondary end-users). The gathered health data is combined with an a priori individual online risk assessment as part of a personalised health plan and personal health record. The initial assessment allows personalising the intervention to individual end-users using pre-defined algorithms based on international classifications and guidelines. Furthermore, the enhanced SENACA prototype will include motivational behaviour-change and social interaction elements for motivational support.

SENACA aims at “blended” behaviour change and intrinsic motivation with constant feedback. The user will get personalized weekly online feedback on performed tasks (activity, nutrition, health literacy). The language of the formal care goals and suggested protocols will deal with common denominators and final common pathways of most chronic diseases including the

three of the study (such as functioning, mood and depression, confusion, falls, abuse and social isolation). In this way USECARE and formal care will best interface, goals will be shared and conflicts avoided. This methodology will enable the enhanced prototype system to take most weight and importance with the three chronic conditions but keep responsibility with the patient in general regarding the formal care.

A behaviour economics (BE) intervention on activity to be tested has already been designed (addressing both informal caregivers and patients), a secondary one is planned on nutrition.

Figure 2. Set-up enhanced SENACA prototype

The following are the *core components and features* of the enhanced SENACA prototype:

I) a website (with secured login) and a complementary smartphone application, both for older community-dwelling adults and informal caregivers, which is at the centre of the structured self-management programme that includes five main elements:

1) *personal program* that can be accessed during the trial with personal computers, notebooks or mobile devices owned by end-users

- *Personal goals / overview*: the end-user's goals pre-defined with consent of the responsible physician focussing on different health indicators, amongst others weight and blood pressure. These goals are targeted within 50 days and should improve until the end of the study period.
- *Health data*: measured either daily or weekly by monitoring devices (see II)
- *Medication adherence*: full list of all prescriptions with three times a weekly documentation of intake by end-users
- *Nutrition*: an online dietary assessment developed and validated in cooperation with leading Swiss experts (Institute of Epidemiology, Biostatistics and Prevention EBPI, University of Zurich; Institute for Cardiovascular Rehabilitation, Inselspital Bern)
- *Physical activity*: personalised advice for endurance (same as above) and strength based on the primary end-user's physical constitution assessed by physician. A special program will be modified for the challenged after elective hip/knee replacement with

specific personalized program for the particular person according to his or her condition.
- *Health-related evidence-based knowledge*: an overview of modules and chapters of the SENACA knowledge platform

2) *personal logbook*, where tasks mentioned in the program are confirmed by the end-users on a daily basis. Health data and some activities are automatically collected via the wireless mobile devices. Medication- and nutrition-related activities (i.e. intake of medicines, calories per meal) have to be confirmed manually by the end-users. Unattended tasks are indicated.

3) *personal statistics*, which is a descriptive statistics section of already collected health data including its constantly updated visualisation

4) *personal health record*, which includes personal data from end-users

5) *knowledge base* including evidence-based information adapted in plain language on hypertension, chronic heart failure, type 2 diabetes and chronic obstructive pulmonary disease (on causes, signs and symptoms, diagnosis, prevention and treatment).

II) home-monitoring devices collecting health data of the participants. These will be transferred using Bluetooth technology to a "data aggregator" for encryption and transmission to a dedicated high security server. In the trial, the following devices will be used:

- Blood pressure, heart rate — OMRON 708-BT
- Weight, body fat — OMRON 206-BT
- Physical Activity — Striive fusion
- Sp02, heart rate — NONIN Onyx II BT
- Spirometry — Vitalograph Asma-1
- Fasting Glucose — MyGlucoHealth

Study participants will receive training provided by USECARE affiliated organizations at baseline data collection to introduce them to the intervention tool (baseline questionnaire filled out before training starts). The training will include reporting methodology and appropriate use of the SENACA hardware delivered in a pre-configured carrying case. One to two days of practicing connection to the national centre and use of hardware will take place after the training session from the private home of the participants. Two attempts to use hardware and deliver data will be performed prior to initiation of the study. Then, study participants will use the website and monitoring devices on a frequent basis. Failure to communicate or use the hardware will be supported and fixed by the national team. An inability of participants to perform training tasks will be recorded and analysed using standard technology acceptance measurements and qualitative methods (phone interviews).

The study participants will be instructed to use the enhanced SENACA prototype at home up to 3-months (100 days). They will visit local healthcare providers three times for standard clinical procedures (i. e. laboratory tests). Suggested care plans will be provided and shared with end-users (and summary of visit reports are to be provided by the nurse to the participant to share with her or his doctor if needed).

All study participants – if finished the self-management program as prescribed for a duration of six months and continuing to actively use the system – will be offered the complete system for free including a further half-year of service cost.

2.2.4 Theoretical framework for usability study

The Part I preliminary studies within USECARE AAL are guided by an often used framework to understanding older adults' usage and non-usage of modern technology, the *technology acceptance model (TAM),* which is considered to be valid and robust (Davis, 1989; King & He, 2006; Holden & Karsh, 2010). In its original version, the intention to use technology (often described as technology acceptance) is determined by two key constructs: *perceived usefulness (PU)*, defined as the extent to which people believe that technology will help them perform their task and *perceived ease of use* (PEOU) which indicates the degree to which a person believes that using a particular system would be free of effort (Davis, 1989; Straub, Keil & Brenner, 1997). A system high in perceived usefulness is one for which a user believes in the existence of positive use-performance relationship, making perceived usefulness the most important predictor of technology acceptance. The TAM has been widely field-tested and enhanced by several researchers, e.g. to further concentrate on influencing context factors (Venkatesh, 2000) or to assign the key determinants in a temporal order (Peek et al., 2014). Further analyses show that the key constructs PU and PEOU can be predicted by personality traits of potential users so that those with high levels of optimism and innovativeness and low levels of insecurity and discomfort have a higher probability to perceive technology as useful and as easy to use (Walczuch et al., 2007). The determinants of the original TAM will be tailored to the setting of USECARE AAL.

Following the TAM's key constructs, *usability* for this study can be defined the ease with which a system can be learned and used (De Vito Dabbs et al., 2009; Preece et al., 1994). This includes, amongst others, *learnability* (ease with which a device can be learned)*, effectiveness* (perceived usefulness for supporting intended tasks)*, efficiency* (perceived ease with which the device can be used)*, errors* (low frequency, severity of errors and easy recovery)*,* and *user satisfaction* (pleasance of use) (see annex 2a). Other constructs like *memorability* (ease with which users can return to the system without relearn) and *flexibility* (variety of ways to achieve intended tasks) will not be addressed due to the research design.

2.2.5 Variables and Measurements

To evaluate the usability (Part I) and evolution of various parameters hypothesized to be responsive to the enhanced SENACA prototype (Part II), the following variables will be addressed and measured with measurements listed in table 3 (additional information on parameters and questionnaires is also listed in the annex section):

Table 3. Overview variables and measurements

Parameters	Mode	Variable	Description	Definition
Socio-demographics	Self-reported	Age		Year of birth
		Sex		Sex of participants
		Education		Number of years in education and highest degree
		Work status		Work status
		Marital status		Legal status
		Cohabitation		Living arrangement
		Nationality		Nationality of respondent & Language skills
		Caregiver relation		Person who is considered as the most important caregiver

Table 4. Aims Part Ia: preliminary study (usability)

Usability	Self-reported	Perceived Ease of Use		Efficiency
		Perceived Usefulness		Effectiveness
		Intention to Use (subjective)		Planned behaviour of technology acceptance
		Acceptance (subjective)	Process parameters	Uptake, adherence, frequency, variety and intensity of use
		Refusal (subjective)		Reasons for not accepting the product
		Errors		Number and type of problems reported

		User satisfaction		PSSUQ
	Automatically	Relative frequency of usage of SENACA's modules		Record of the usage of single components that are not mandatory
		Adherence to SENACA prototype		Number of days within program from initiation to discontinuation (time to event)
		Errors of SENACA system during implementation		Number and type of technical problems occurring
eHealth & Technology Literacy Readiness	Self-reported	Optimism/ Innovativeness/ Insecurity/ Discomfort	Factors that measure personal traits	item battery of TRI
		eHealth Literacy	Factors that measure health literacy related to use of electronic devices	eHEALS

Table 5. Aims Part II: pre-experimental design (outcome parameters SENACA effects)

Clinical	Automatically	Body Fat		fat proportion of body (%)
		Weight		Body weight in kg
		Blood Pressure		Systolic / diastolic mmHg
		Pulse		per minute
		SpO2 (only where needed)		in %
		Fasting glucose		mmol
		One-second forced exhalation, FEV1		%
	Laboratory	Cholesterol, LDL		mmol
		Cholesterol, HDL		mmol
		Total cholesterol		mmol
		Triglyceride		mmol
		HbA1c		mmol
		BNP		pg/ml
	Self-reported	Height		Centimetres

Self-efficacy, health-related QoL & burden of care	Self-reported	Quality of Life	Factors that measure the overall life quality	EQ5D5L: 5 Dimensions Mobility, Self-Care, Usual Activities, Pain/Discomfort, Anxiety/Depression
		Health status		Question to measure overall health status
		Self-efficacy		Self-efficacy for managing chronic disease scale (SES6)
		Burden of care		(question from IL, Jacob Gindin)
Behavioural	Self-reported	Nutrition & Alcohol consumption		Weekly unit consumption
		Physical activity		Exercise and walking
		Smoking		Smoking behaviour
	Automatically	Physical activity		Personal logbook/ pedometer

2.2.6 Data collection

The data collection for this study is intended to collect sufficient and appropriate data to identify usability-related issues and to observe parameters on health-related behaviour and clinical outcomes. Once ethics approval is granted, the primary investigator (PI) and the coordinator of USECARE will liaise with the co-investigators in the participating countries and their collaborating clinical settings. When informed consent of eligible participants is obtained, empirical data will be collected by the prototype's measurements (automatically and self-reported), laboratory tests of blood samples, self-reported written questionnaires and using qualitative research methods (interviews).

Measurements

Time points of measurements before, during and after the implementation of the prototype are listed in table 6:

Table 6. Overview time points of measurements

		Time points				
Parameters	**Variable**	**automatically**	**(bi-)/ weekly**	**Day 0**	**Day 50**	**Day 100**
Socio-demographics	**Age**			X		
	Sex			X		
	Education			X		
	Work status			X		
	Marital status			X		
	Cohabitation			X		
	Nationality			X		
Clinical	**Body Fat**	X		X		
	Blood Pressure	X		X		
	Pulse	X		X		
	SpO2	X		X		
	Fasting glucose	X		X		
	One-second forced exhalation, FEV1	X				
	Cholesterol, LDL			X	X	X
	Cholesterol, HDL			X	X	X
	Total cholesterol			X	X	X
	Triglyceride			X	X	X
	HbA1c			X	X	X
	Weight			X	X	X
	Height			X		

	Disease history			X		
Self-efficacy and Health-related QoL	Quality of Life (EQ5D-5L)		(X)	X	X	X
	health status		(X)	X	X	X
	Self-efficacy for managing chronic disease			X	X	X
Behavioural	Nutrition & Alcohol		(X)	X	X	X
	Smoking			X	X	X
	Physical activity	X		X	X	X
Usability	Perceived Ease of Use (Efficiency)			X	X	X
	Perceived Usefulness (Effectiveness)			X	X	X
	Intention to Use (subjective)			X	X	X
	Acceptance (objective)			X	X	X
	Prototype-adherence	X			X	X
	User satisfaction				X	X
	Relative frequency of usage of SENACA's modules	X			X	X
	Errors	X			X	X
eHealth Literacy & Technology Readiness	Individual personal traits predicting technology acceptance			X		
	eHEALS (8 items)			X	X	X

Interviews

To gain a deeper understanding of the end-user's experience with the SENACA prototype, a series of semi-structured interviews (Creswell, 2007) with the study participants will be carried

out in the respective languages of the countries involved. Those community-dwelling older adults and informal caregivers finishing the SENACA program will be invited to participate in an interview as will be the ones who potentially discontinue before completing the program. The invitation starts two or three days after completion or drop-out and interviews will be conducted by phone. The intention of reaching data saturation will guide the recruitment procedure and number of participants invited.

By applying a semi-structured interview guide and using open-ended questions, the study participants will be encouraged to elaborate and to describe their experiences with the SENACA prototype in detail (see annex 6). Participant answers will be recorded digitally, transcribed verbatim and translated into English for later analysis.

2.2.7 Ethical considerations

Ethical approval will be obtained in the participating countries before recruiting participants for the study. The participants will receive written information about the study objectives and procedures (see annex 8). They will also be informed about possible risks and benefits including the further use of the system for 12 months at no cost. They will be advised about their right to discontinue their participation at any time. Written informed consent will be obtained.

A high security server will be used for data security of personal information of participants, which will be encrypted for transmission via the data aggregator installed in their households. Throughout the study, investigators will have access to the participants' personal health record using their consent log-in and password (same procedure holds for the treating resident physician / healthcare provider and the informal caregiver, identified on the basis of the SuisseID solution).

2.2.8 Data analysis

Explorative and descriptive data analyses will mainly be performed in this field-test study with a relatively small sample size.

First, descriptive analysis on usability will give a general overview of how users, both informal carers and patients, view SENACA before having used it. The findings will be compared with perceived usability after having experienced it for the whole intervention period (up to day 100). This will provide insights on practical implications on the design and introduction of SENACA. A qualitative analysis on break-offs and non-response further completes the findings by exploring the barriers and drivers of usage. In addition to that, the usage of the several components of SENACA will be compared regarding frequency and intensity to explore which aspects are more or less accepted by the user groups.

In a second step, the clinical and behavioural parameters and quality of life will be screened at baseline measurement. This initial description gives further insights into the characteristics of the sample. Changes in parameters over time will be explored to gain insight into the functionality of SENACA.

Overall, mean values will be compared on the basis of non-parametric tests to identify significant differences between groups. Even though the study does not meet the requirements of an experimental design, the ex-ante and ex post measurement allows monitoring changes of the observed variables. Bias due to non-observable errors may be possible.

Data from qualitative study parts (i.e. interview transcripts, content from open-ended questions or user forums) will be coded applying thematic analysis (Bradley, Curry & Devers, 2007) in order to categorize the data as well as to identify patterns leading to a nuanced evaluation of the usability of SENACA from a technological, educational and behaviour perspective. The qualitative analysis will be guided by taxonomies and frameworks on the subject of matter to be used as sensitizing concepts, for instance Michie et al. (2013) or Greenhalgh et al.(2015). Computer-aided qualitative data analysis (most likely MaxQDA®) will be used for coding and synthesising the findings.

Supplementary analysis

In addition to the previously described analyses of USECARE AAL, in Israel, a supplementary analysis will be performed. The Assuta team will perform the interRAI Community Health Assessment (CHA) with the Israeli participants in order to assess in depth their health conditions, functioning, cognition, mood, pain, continents, mobility, physical and social environment, care needs, as well as health care utilization. The assessment will determine risks and treatable conditions and algorithmically produce care goals to do, as protocols for the formal care givers. This system is highly reliable and valid and in use in the Assuta environment for care of old people. The interRAI system is in use in 40 countries and sometimes demanded by care providers, insurers, and governments (US, Canada, Finland, Belgium, Hong-Kong, New-Zealand and others). This will create a parallel track of formal and informal care to be investigated. USECARE is important way to empower informal caregivers. However it is always additional to the formal care. This structured and well-determined formal care system will produce quality interRAI data, which will be compared to the automated and self-reported measurements from the USECARE AAL study.

2.2.9 Limitations

A longitudinal approach is used in this study to examine changes over time and to identify the usability as well as adherence of participants with the programme as indicators of its usefulness in everyday life. However, the adopted design and study procedures will lack the sufficient statistical power to detect significant findings and may result in potential bias given the lack of a control group and lack of randomisation in recruiting participants. Therefore, the analysis is primarily descriptive and will be used to gain in-depth insight into the user experience with the enhanced SENACA prototype in participating European countries.

2.3 Conclusion

At the end of this study, we expect to have insights on how to further improve a self-management support system for community-dwelling older adults and their informal caregivers that is useful in everyday life and may be related to behaviour change, improved clinical outcomes and quality of life. Further research including a controlled trial is needed to test the effectiveness of the enhanced SENACA prototype. Findings from this study can be used to identify those features of the prototype that should be optimised to inform an on-going improvement of the self-management support system for its scalability in the respective European countries.

3 SENECA web-platform usability tests

3.1 Introduction

USECARE is a 2-year EU financed project (2015-16) with the objective of implementing and testing a self-management tool for people with chronic diseases. Partners in Israel, Norway and Switzerland will host pilot sites, recruit users and see to that the implementation, testing and data gathering go as planned. The objective is to evaluate the use of the self-management system, focusing on the use of the system (usability, user-friendliness, satisfaction) and if parameters connected to QoL and some health parameters stabilize or change during the project period.

During the intervention patients in three countries (Israel, Norway and Switzerland) will be using medical devices to record health related data (different patient groups will be using medical devices according to their symptoms). Bluetooth will transmit the data via a HUB to a database. The patients can then access their personal data on a web-platform. The patients will be able to set target values for the health related parameters, making plans for activities, manage medication, read about the disease and register information in a diary. Every patients are to name an informal caregiver who also will using the web-platform. The aim is to motivate the patients to change behaviour based on relevant information and continuously updated health related information. Informal caregivers will get opportunity to support the patient in her or his effort, based on the same data

Before the study started, we recruited test users in the three pilot countries to evaluate the SENACA system in terms of usability and feasibility of the system. The test users were recruited based on criteria that resembled the ones that are to be used for the recruiting of the patients, except that they are not necessarily patients. The test users were equipped with the same medical devices that the patients are going to use during the intervention.

3.1.1 Usability testing

Usability testing is a technique used to evaluate a product by testing it with users**.** Usability is defined in terms of aspects, such as time to learn how to use the system, user's errors, time to fulfill a task, user's satisfaction and acceptability, etc.

As Jakob Nielsen points out elaborating usability tests with a lot of users are a waste of resources (Nielsen, 2000). You learn less and less for the extra users you add because there will be overlap in what you saw with the previous users. However, people are different and you find something particular with new users, but after added some extra users you will be observing the same thing repeatedly. Nielsen is claiming that after the fifth users, you do not get much new information. 15 users is enough to identify all the usability problems in a design, but Nielsen is advocating spending resources on 3 studies with 5 users each rather than recruiting 15 users. It is this iterative design approach that allows you to improve the design gradually by letting the users test the redesigned versions of the system.

When users are very different you need to test with additional users. Still he thinks that different groups of users have many things in common, because usability problems are related to the way people interact with a web site (Nielsen, 2000). Nielsen is advocating small numbers of test users, even when we anticipate that there are several highly distinct groups of users. You do not need to include as many users as you need in a test with a single group of users, he

says, and recommends that you recruit 3 users from each group if you are testing three or more groups of users.

Different methods can be applied when doing usability tests. The Hallway technique is a quick and cheap method were you invite people passing in a hallway to use the system. The developers or researchers can observe while the users operate the system. Another technique is to invite test users that have some of the same characteristics as the real users. It is more resource demanding than the Hallway method but potentially we will get more valid information, especially if we anticipate that some background variables will affect their experiences and views. The test users are then invited to do specific tasks while the developers, researcher or another person are observing how they are performing the tasks. The session can be followed up by an interview and/or a questionnaire in order to get a more comprehensive understanding of what the users think about the functional and non-functional (look and feel, performance etc.) aspects of the system. The use of interview is more resource demanding than questionnaire, but by interviewing, we are getting richer information.

A third technique is to let users use the system in their own home environment or at work. Test users are invited based on some variables that are similar to the potential users. The users will be using the system for a longer period and perform specified tasks. We can use different methods to gather information about how the users react to the system and what kind of problems they encounter. The test users can give instant feedback (e-mail, drop box etc.) or they can respond after a period, using interviews (individual or focus group interview) and/or give feedback via a questionnaire (open-ended questions included).

3.1.2 Qualitative and quantitative methods

Both qualitative and quantitative methods can be used when performing usability tests (Nielsen 2000, 2006). When you are using qualitative methods you normally use observation or/and qualitative interviews. Observation in social science means studying or gather information of people performing activities. In usability studies, you typically watch users while they are handling or using the technology. Interviews is a method where you ask the users orally regarding what they think about usability aspects, e.g. subjective satisfaction. You can ask questions while observing the users performing activities and/or after the users have finished their activities. Quantitative studies can be performed by measuring the time it takes to perform a specific task, errors etc. or by using questionnaires to get information on how the users perceive the technology. Both qualitative and quantitative methods have their strengths and weaknesses. Qualitative studies can be easy to organize if you only need a few test users and you are able gather rich information regarding how the users perceive the technology. The disadvantages are that you only are able to include a few test user compared with quantitative methods using questionnaires, and that it is time consuming to analyze the data. By using quantitative methods, you are able to include more test user and it is easier to compare data across users and user groups as the data is highly structured. However, including many users is expensive and since the studies are more or less predefined, for example when using questionnaire, there are always a possibility of ending up with misleading data (Nielsen, 2000).

Mixed methods studies, can be applied when conducting usability tests. Mixed methods studies is a methodology for conducting studies that involves collecting and analyzing both qualitative and quantitative data (Wisdom and Creswell, 2013). By mixing both qualitative and

quantitative data, you get data that easily can be compared between users and data that that give us richer information regarding what the users think about the technology.

3.2 Methods

3.2.1 Overview

The patients will be using both a website and medical equipment during the trial. The aim of the pre-test was to test both the web site and the medical equipment as well as the connectivity and transmitting of data between the medical equipment and the web site.

In our test study, we applied both qualitative and quantitative methods. During the introduction to the system, we observed the users handle the medical equipment. We saw how they fastened the blood pressure band around their arm, attached the step counter to the arm and handled the electronic scale. During the observation, we were able to ask questions and the users could make comments. This gave us insight into what it takes to teach people how to use the devices.

During and after the test period, we interviewed the test users. We had developed an interview guide that included 4 aspects: 1) usability of the system, 2) the different modules and the devices, 3) graphical presentation and meaning of the colors used, and 4) problems encountered. We interviewed the test users separately, although we could have used focus group interviews. Focus group interview is less resource demanding then doing several individual interviews, and gives the users the opportunity to react on each other's statements or questions (Kitzinger, 1995). However, the small numbers of test users in each country made convenient to do individual interviews. The advantage of individual interviews is that the test users are able to talk freely, while focus groups are more prone to be dominated by a talkative person.

After the tests, we gave the test users a questionnaire to fill out. The questionnaire used a scale, from 0-5, and presented a set of statements regarding 15 aspects, including: to setup of the SENACA system, navigate within the system, leaning to use the system, readability of the content, steps to accomplish the tasks, error messages, usability of the modules and the medical devices. The questionnaire contained free text fields where the test users could write down their own comments to elaborate their marking on the scale. The scale will enable us to compare results between different users and aspects, and to identify outliers, observations that markedly deviate from other values.

3.2.2 Recruitment and start-up procedure in Norway

We recruited three test users in June 2016. Our goal was to recruit both genders, and we adopted one of the criteria from the study protocol, that test users should be above 50 years old. They should also be acquainted with the use of computers, have access to Wi-Fi in their homes and could find time to test both the medical devices and the web site.

Of the three users, two them were females and the third person was a male. They were all willing to use the system for a three weeks period and to share their thoughts regarding the usability, orally and in writing. We recommended that they should try to use the system on a daily basis, and to report in mail if they encountered major problems.

Before the tests started, the test users had to fill in a questionnaire related to some personal background data (gender, age, address, height, e-mail address, activity etc.) in order to be registered as a user of the SENACA system. Some of the data were vital to the configuring of the medical devices. We received the medical devices in July 2016.

We handed out the medical equipment meant for people with heart failure to the test users in July 2016. The package included scales, blood pressure devices and activity trackers for 3 test users, plus an extra package to be used by the project team. A member of the project, who's an expert on medical devices and a technical adviser, met the test-users individually due to that the test users had different vacation schedules. The member introduced the users to the devices and performed a hands-on (or feet-on for the weight) experience with the devices. The introduction lasted for half an hour. The test users also got manuals for how to use the devices and we informed them that they could start use the medical devices.

In late August 2016 the users were able to access the Norwegian version of the SENACA website. EMN made an account for each of the three users and configured the system based on the data provided by the test users. We told the users to log on to platform and that they had an option to change the password.

3.2.3 Recruitment and start-up procedure in Switzerland

We recruited four users in September 2016. Our goal was to recruit both gender, and we adopted one of the criteria from the study protocol, that test users should be above 50 years old. They should also be acquainted with the use of computers, have access to Wi-Fi in their homes and could find time to test both the medical devices and the web site.

Of the four users, three them were males and the fourth person was a female, the youngest 61, the oldest 78. They were all willing to use the system for a 10 days period and to share their thoughts regarding the usability, orally and in filling out the report template. We recommended that they should try to use the system on a daily basis and to call us in case of problems

Before the tests started, the test users had to fill in a questionnaire related to some personal background data in order to be registered as a user of the SENACA system. Some of the data were vital to the configuring of the medical devices.

We handed out the SENACA basis system including included scale, blood pressure device activity tracker and connectivity hub to each of the 4 test users. A member of our team introduced to the users to the pre-configured devices at our site. The introduction lasted for half an hour. The test users also got manuals for how to use the devices and we informed them that they could start use the system at home.

3.2.4 Recruitment and start-up procedure in Israel

The recruitment process has started and the results will be ready by the end of the month. Table 7 shows the number of test users, gender, age and for how long teste period lasted per country.

Table 7. Number of test users, gender, age and for how long test period lasted.

Country	N	Male	Female	Age	Test period
Norway	3	1	2	50+	21 days
Switzerland	4	3	1	50+	10 days

3.2.5 Tasks do be done during the test period

We told the test users to use the system and perform tasks on a regular basis. Registering of personal data, management of the user account (user name and password) and configuring of the medical devices had already been done by the project partners (EMN and UNN). These tasks have not been tested by the test users and this is something that also will be done by the project members when we hand out the systems to the patients and the informal caregivers.

We invited the test users to use the medical devices, to check the result in the SENACA website and to navigate through the system and perform tasks. After having logged in to the SENACA website for the first time, the user could perform the following tasks:

1. Nutrition: You have to answer a questionnaire regarding nutrition, health status, activities etc.
2. Choose 3 specific items from a list of nutrition items you want to monitor. Register what you have been eating on daily basis. Check your daily and weekly statistics.
3. Activity: Check the list of activities and exercises to be performed.
4. Register daily activities and exercises. Check the videos about how to perform the activities.
5. Check monitoring data measured with the delivered clinical devices: scale, blood pressure and activity tracker.
6. Medication: register medications and when to take them. Confirm that you have taken the medications. Register spontaneously taken medicines.
7. Statistics: check your values in the statistics (at the end of the testing period).
8. Health literacy: check the knowledge modules and the knowledge tests that you can perform.

We invited the test users to record any problems they encountered while they were using the system and report it to the members of the project team

3.2.6 Usability questionnaire

We invited the users to answer a questionnaire with statements regarding the usability of the SENACA system. They were asked to evaluate different devices and functions on scale from 0 to 5. The result is presented in table 8.

Table 8. Result from usability questionnaire in Norway and Switzerland (n=7).

		0	1	2	3	4	5	
Learning to use the system	Difficult					2	4	Easy
Navigate	Difficult				1	4	1	Easy
Readability of content	Difficult				1	4	1	Easy
Few steps as possible	Disagree	1			1	4	1	Agree
Error messages	Unhelpful				2	1	3	Helpful
Graphical presentation	Confusing					2	5	Very clear
Easy to use: Monitoring	Disagree					1	6	Agree
Easy to use: Medication	Disagree					3	3	Agree
Easy to use: Nutrition	Disagree			1	2	2	1	Agree
Easy to use: Activity	Disagree				1	1	4	Agree
Easy to use: Health literacy	Disagree	1				3	1	Agree
Easy to use; blood pressure device	Disagree						7	Agree
Easy to use: Scale	Disagree						7	Agree
Easy to use: Activity tracker	Disagree				2	2	3	Agree

Overall, the numbers from the questionnaire show that the test users are quite or very satisfied with the system. Looking at all the functionalities, we see that majority of the test users give them a positive score, 3-5, and for many of the functionalities we see that a majority of the test users give them a score of 4 or 5. If we look at the statements regarding usability of the system as a whole, statement 1 to 7, we see that the majority of the test users are satisfied with the system.

When we look at the statements regarding the five basic functions that the system offers (monitoring, medication, nutrition, activity, and health literacy) we see some differences. Although a majority say it is quite or very easy to use these functionalities, we see that there are one person who mark the statement regarding usability of the Nutrition module with 2 and one person who mark the statement with 1. We also see that the function Nutrition do not have as many top scores as the other functions, except for Health literacy. Although the users found it quite easy to use the Health literacy module, except for one of the users, we see that only five persons have answered the questions regarding Health literacy.

When we look at the scores for the medical devices, we see that the usability of both the scale and the blood pressure device get top scores. Although all the test users find the usability of the activity tracker to be acceptable there are two persons who give it a score of 3 and two give it score of 4. Compared with the score of the scale and the blood pressure device we can conclude that the test persons think that the usability of the activity tracker could be better.

3.3 Results

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The users were invited to share their impressions of the usability both in interviews and in free text answers to the statements in the questionnaire. The interviews were conducted based on an interview guide. The interviews and open-ended or free text questions let the test users use their own words in describing their experiences with the use of the SENACA system.

3.3.1 Views about the usability of the SENACA web-platform in general

The test users were able to use the system rather quickly after they had got access to the web-platform. One of the test persons commented that the system is very comprehensive and that he/she only have been using parts of it (NO1). We will see later in the report that several test users say that they have not been using all the modules on a regular basis.

After the users have logged into the system, they are able navigate through the system from the dashboard. They reported that they were able to activate all the relevant functions. One of the test users said the web-program is a little bit complicated, and in order to fully use the program the users have to be accustomed to the use of computer programs (NO). One of the Swiss test users said that at first it was not so clear-cut, but after have been using the system he/she found it to be very easy to use. Another user said that sometimes he/she got lost, but that especially happened in the beginning before he/she had accustomed to the use of the program. When he/she got lost he/she would go back to the main menu, but sometimes he/she was not able to find the function he/she had intended to activate (NO).

One of the test users said it was difficult to answer that the statement "**the system requires the fewest steps possible to accomplish what I want to do with it",** as he/she is not a computer expert (NO). Probably this is a question that it is difficult to answer when you do not have another program to make a comparison. However, one of the users commented on the structure of the program and he/she sometimes found it a bit too complex (SW). A third user focused more on the time it took to accomplish what he/she wanted as the program didn't always respond quickly, and sometimes the program is hanging, and that meant he/she had to sit and wait to fulfil the task (NO).

The test users have not encountered many errors, and many of them have not seen an error messages. However, several users have encountered one specific error. Sometimes during the test period, they have experienced that data from the scale has not been transmitted to the web-platform. Normally they would just use the scale one more time. One of the users reported that he/she only experienced errors a couple of times with the scale and he/she found the error messages to be helpful (NO). One of the Swiss users said that activity tracker sometimes did not transmit all the data, and there was no error messages (SW). This is something that Norwegian also have experienced but they have noticed that the data have been transmitted later.

The users found the graphical presentation to be adequate and made it quite easy to find and activate the relevant modules.

3.3.2 Usability of the modules

The SENACA web-platform offers the users to activate different modules. Many of the users were commenting on the Nutrition module. Before you activate the module, you have to answer a set of question regarding your food intake. One of the users found that going through the questionnaire and registering the daily intake of three items was too time-consuming, and there were this problem of remembering past nutrition (SW). Another user would like to have a module where he/she could register all the food he/she has been consuming during the day and not just the three items he/she was to focus especially on (NO). A third user was asking about the possibility of administering the data regarding nutrition when he/she had forgot to register the nutrition. He/she felt it is demotivating when you get a message on the dashboard telling that you have not completed a task.

Medication is module that the users have not used so often, maybe because many of the users do not use medicine. One of the users, who is using medicine, said that is was of no relevance since he/she uses a medical dispenser (SW). Another user, who have tried the medication module but only using fake data, said that system kept reminding the user when he/she had forgotten to take the medicine even though he/she could not just take extra medicine the day after (NO). One solution would be just to register that you have taken medicine, but then the data regarding medicine adherence is not correct.

The users found it easy to use the activity tracker module. One of the users commented on checking the SENACA website in the morning. He/she said that when h/she accesses the web-site in the morning you get a "Caution" about physical activity while he/she hardly had started the day (NO). Is it possible to show the results from the activity tracker from the day before, he/she asked?

The test users have tested the blood pressure device on a more or less regular basis. They all said it was easy to use the module. However, two of the users were commenting on the blood pressure statistics and thought that data of the blood pressure (systolic and diastolic) should be presented in one table and not in two tables (NO).

Although the users found it quite easy to use the health literacy module, several users were commenting on the content. As one the users said, the layout is good but the content is to complex (SW). Another user said that the information regarding health aspects was ok, but it was not easy to understand all the medical stuff, especially when some of the texts was in English. A third user was also commenting on the lay-out. He/she said that there was too much information to be read, and it would have been easier if the text had been divided into smaller chapters.

3.3.3 To use the devices

The users found both the blood pressure device and the scale easy to use. However, one of the users said it was difficult to understand all the data from the scale (NO). The one thing several users, both in Switzerland and in Norway, have been commenting on is that sometimes the data from the scale is not transmitted to the web-platform, or at least that they are not able to see the data immediately.

They all said that tracker is easy to use. However, the users made some comments about the usability. One users said that it was difficult to mount the tracker at first, but one gets used to it (SW). Another user said the activity should be equipped with a display so that users are able to get updated about the daily activities without having to be near the HUB in order to transmit the data and then have to log on to a computer (NO)[6]. There was also comment regarding accuracy of the tracker where the user said that he/she was not sure about the accuracy (SW).

3.3.4 General comments

We asked the users if they had any general comments about the SENACA system. One of the users in Switzerland said that he/she really liked the SENACA system and kept the system for four weeks and reported that he/she had lost weight during that period (SW). One of the users in Norway also kept the system for longer period than planned (NO). However, two of the users in Switzerland were more dubious about the system. One of the users said that although

[6] The first activity trackers we tested in Norway did not have a display.

he/she rated the system overall as solid and useful, he/she questions the time needed for continuous use. The other user also commented the time needed to use the system on a daily basis, as he/she are quite active and in good shape.

3.3.5 List of problems/failures that need to fixed

During the test, we invited the users to report functional and performance problems or errors they encountered during the tests. The list describes errors that needed to fixed during the test period.

Table 9. Description of functional problems encountered during the test period.

ID	Site	Problem/date	Comments
1	No	When testing devices, we got data from the blood pressure measurement device after a few seconds. But the step counter do not show any data on screen. This despite we can see the hub is blinking blue after receiving Bluetooth data. /7.9.2016	Problem fixed
2	No	A scale was not in correct mode for Bluetooth communication. /8.9.2016.	UNN: It had to be re-set with a mobile app: OMRON Tx Toggler. This was done in cooperation (via Skype) with Herbert Hotz, EMN, Switzerland.
3	No	Our test users have been given the advice from Senaca to eat more fruits. But there is nowhere she/he can register that she/he has actually been eating fruit /7.09.2016	Problem fixed
4	No	Id 2163 says “only DAY day until your SENACA Health Program starts!” But the SENACA platform does not specify a number of days. This may also be true for other specifications of days?./ 9.9.2016.	Problem fixed

There were four functional errors registered during the start of the pre-test in Norway. They were all fixed. Interestingly one of the errors we were able to fix in Norway with the help of EMN via Skype.

3.4 Conclusion

The test users in Norway and Switzerland found the SENACA system to be highly feasible and acceptable. They were able to use the system after a short introduction made by members of the AAL UseCare project. The users tested both the SENACA web-platform and three devices (blood pressure, scale and activity tracker) on a regular basis. After the test period, they filled in a questionnaire, including free text questions, and we interviewed them about their reactions. The users reported on the usability of the web-platform as well as the three devices. They found the usability of the web-platform to be acceptable. The users have not encountered many problems, except for problems with scale statistics; sometimes the scale does not transmit the data, at least not immediately, and the activity tracker statistics; the users have to wait to until the information is updated. There were mixed thoughts about the Nutrition module. One user said it was too time consuming, while another thought he/she should have the opportunity to register all the food intake during the day, and not just the three most important items. Some of the users also criticized the Health literacy module for being too time consuming. There were some criticism of the activity tracker. One user was questioning the accuracy of the tracker while another was commenting on the lack of display on the tracker. In general, the test users evaluated the SENACA system positively. This conclusion is supported by the fact that there are users who have been using the system for a longer period than the planned test period.

4 Risk assessment

4.1 Introduction

According to Norwegian legislation[7], data controller and the data processor shall ensure satisfactory data security with regard to *confidentiality*, *integrity* and *availability*. This is in line with European privacy legislation: **Directive 95/46/EC, on protection of personal data[8].** Therefore, we have selected this country to conduct the risk assessment of the platform. The security aspects are defined by ISO in ISO/IEC 27000[9] in the following way:

- **Confidentiality**: The property that information is not made available or disclosed to unauthorized individuals, entities, or processes.
- **Integrity:** The property of accuracy and completeness of information. This means that data cannot be modified in an unauthorized or undetected manner.
- **Availability**: The property of information being accessible and usable upon demand by authorized users.

This risk assessment is conducted with regard to these information security aspects. The Norwegian "Personal Data Regulations"[10] section 2-4 states, about risk assessment:

> *"The data controller shall carry out a risk assessment in order to determine the probability and consequences of breaches of security. A new risk assessment shall be carried out in the event of changes of significance for information security.*
>
> *The result of the risk assessment shall be compared with the established criteria for acceptable risk associated with the processing of personal data" ….*
>
> *"The result of the risk assessment shall be documented."*

NST's method for risk assessment is based on the ISO standard for information security risk management[11]. The method can be summarized in this way:

A structured overview of potential threats and unwanted incidents is set up, based on information from key personnel with knowledge about the service and the technical solution. These persons are usually the system developers and other project members. The threats will include both technical and organizational threats. Information is collected in "brainstorming

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[7] Act of 14 April 2000 no. 31 relating to the processing of personal data [Personal Data Act] http://www.datatilsynet.no/English/Regulations/Personal-Data-Act-/ (link checked 2016-01-13)

LOV-2000-04-14-31 – Lov 14. april 2000 nr. 31 om behandling av person¬opplysninger (Personopplysningsloven). http://lovdata.no/dokument/NL/lov/2000-04-14-31 (link checked 2016-01-13)

LOV-2014-06-20-43 – Lov om helseregistre og behandling av helse¬opplysninger (Helseregisterloven) – in Norwegian only. https://lovdata.no/dokument/NL/lov/2014-06-20-43 (link checked 2016-01-13)

LOV-2014-06-20-42 – Lov om behandling av helse¬opplysninger ved ytelse av helsehjelp (Pasientjournalloven) – in Norwegian only. https://lovdata.no/dokument/NL/lov/2014-06-20-42 (link checked 2016-01-13)

[8] Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data. European Parliament and Council of the European Union, 24 Oct 1995.

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:EN:HTML (link checked 2016-01-13)

[9] ISO/IEC 27000:2014 Information technology – Security Techniques – Information Security Management Systems – Overview and Vocabulary.

[10] Regulations on the processing of personal data [Personal data regulations] http://www.datatilsynet.no/English/Regulations/Personal-Data-Regulations/ (link checked 2016-01-13)

[11] ISO/IEC 27005:2011 Information technology – Security Techniques – Information Security Risk Management.

sessions" in specific risk assessment meetings, or by interviews and dialogue with key personnel.

For each threat, a qualitative value is set for *likelihood* and *consequence*, and the resulting *risk value* for the threat can be calculated. The risk assessment ends up with a proposal for mitigations that can help reducing the risk level[12].

This report documents the risk assessment by describing the identified threats to information security and our analysis of these threats.

4.2 Description of system and service

In Switzerland, a novel web platform has been developed including standardised tools for calculating chronic disease risk and evidence-based health information to increase health literacy. The development of this senior health academy (SENACA, www.senaca.ch) was originally funded by the Swiss State Secretary for Education, Research and Innovation and conducted in close collaboration with health professionals, behavioural scientists and ICT experts as a first step towards user-centred design. It has now evolved to *the SENACA platform*, a structured self-management support system combining telemonitoring devices and a solution for personalized health plans [**Error! Reference source not found.**]. The enhanced SENACA prototype combines monitoring and behavioural change elements with access to evidence-based health information for patients and caregivers.

4.2.1 Service description

The service provided by the SENACA platform is intended for persons with one or more chronic diseases, and their caregivers. It consists of a web-based solution with questionnaires, in addition to automatic transfer of monitoring values for e.g. blood pressure and heart rate, blood glucose, lung capacity (SpO2), body weight, and activity (step counts). Which monitoring parameters that will be collected, depends on which chronic disease the patient has. In Norway, the main target group is patients with chronic heart failures and their informal caregivers.

The gathered health data is combined with an a priori individual online assessment of health, as part of a personalized health plan and personal health record. The initial assessment allows personalizing the intervention to individual end-users using pre-defined algorithms based on international classifications and guidelines.

Study participants will use the SENACA prototype at home for a 3-month period (100 days) and visit local healthcare providers three times for standard clinical procedures (laboratory tests). Users will get personalized weekly online feedback on tasks (activity, nutrition, health literacy) as well as "rewards" (gamification). Informal caregivers will get a short introduction/tasks (e-learning) on motivational interviewing.

[12] This risk assessment was conducted in November-December 2015 and January 2016 by Eva Henriksen. The following key personnel participated in the risk assessment meetings: Per Atle Bakkevoll, Elisabeth Ellefsen Sjaaeng, and Frank Larsen. In addition, some clarifications were obtained in e-mail communication with Herbert Hotz, CTO, Medical Network EMN AG, Switzerland.

Figure 3: SENACA start page with login

The center of the structured self-management program is a web site and a complementary smartphone app[13], both for patients and caregivers. It includes five main elements:

1) *A personal program* that can be accessed by end-users with their own personal computers, notebooks or mobile devices. It collects data like *personal goals,* values from *monitoring devices, medication adherence, nutrition,* and *physical activity.* It also presents relevant *health-related evidence-based knowledge* to the users.
2) *A personal logbook*, where tasks mentioned in the program are confirmed by the end-users on a daily basis. Health data and some activities are automatically collected via the wireless mobile devices. Medication- and nutrition-related activities (i.e. intake of medicines, meals) have to be confirmed manually by the end-users.
3) *Personal statistics*, which is a statistic section of already collected health data including its visualization.
4) *A personal health record*, which includes personal data from end-users.
5) *A knowledge base* including evidence-based information adapted in plain language on hypertension, chronic heart failure, type 2 diabetes and chronic obstructive pulmonary disease (causes, signs and symptoms, diagnosis, prevention and treatment).

[13] No more information about the mobile app is available at this stage.

Study participants will be trained how to use the SENACA website, personal health plan and the tele-monitoring devices, including instructions for technical support. They will take the monitoring devices home in a pre-configured carrying case and, if needed, they will receive local support for set-up at home. Then, study participants will use the website and monitoring devices on a daily basis.

4.2.2 System description

The system to be used in the field-test is an enhanced version of the SENACA prototype. It is a *cloud-based structured self-management support system with tele-monitoring components* designed to be universally-interoperable with different medical devices and applications.

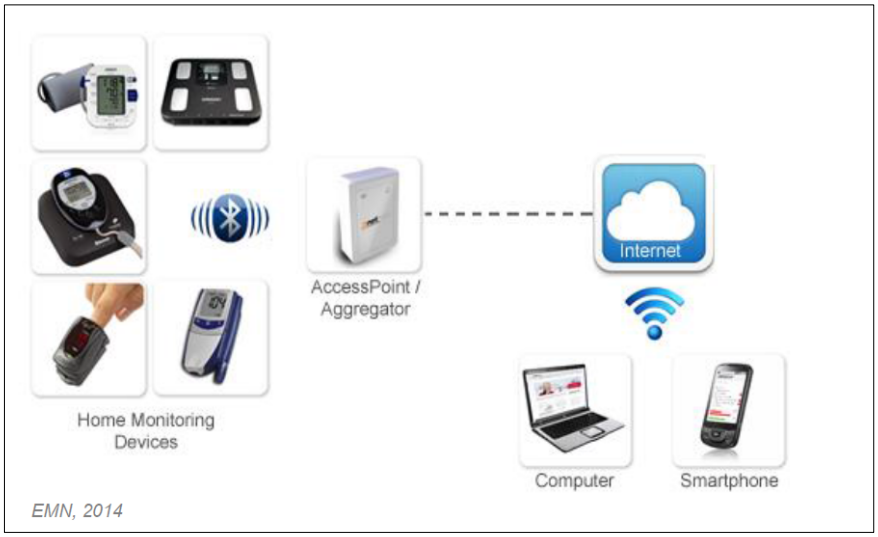
The enhanced SENACA prototype enables end-to-end wireless connectivity and allows end-users to access biometric data via mobile devices (tablets, smart phones) and personal computers by their choice.

SENACA includes a web-based platform with a personalized Health Plan and a Personal Health Record (PHR). Additional equipment are the **home-monitoring devices** collecting health data from the participants. These data will be transferred using Bluetooth technology to a "data aggregator" for encryption and further transmission to a dedicated high security server (**Error! Reference source not found.**).

In the trial, the following devices will be used:

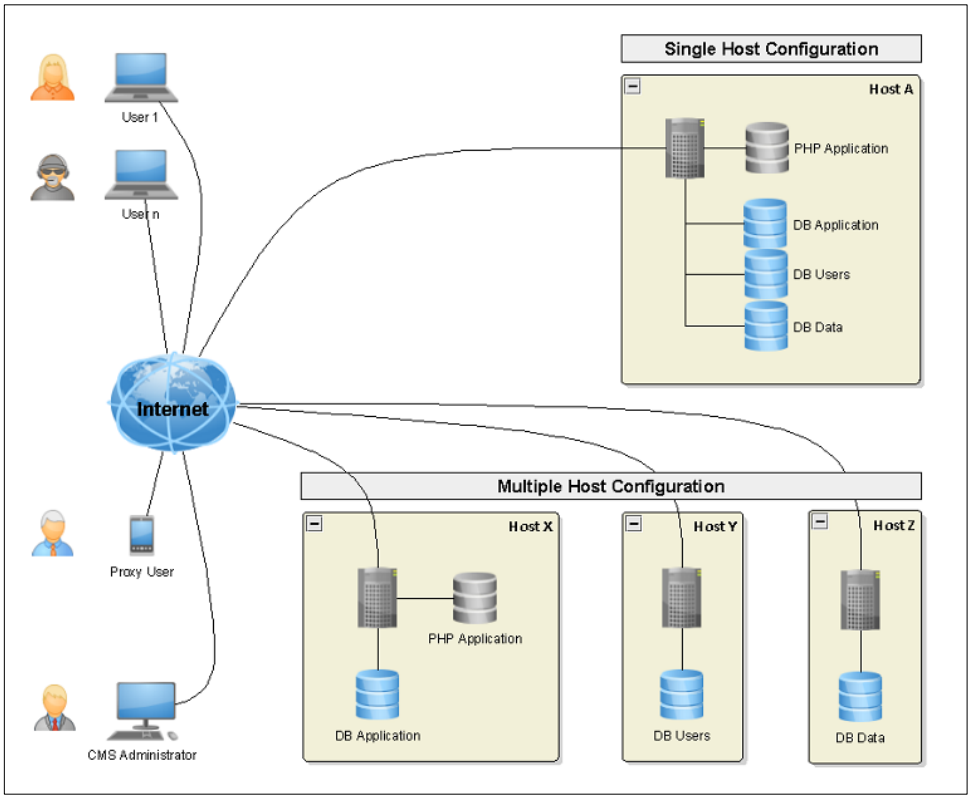
- Blood pressure, heart rate: OMRON 708-BT
- Weight, body fat: OMRON BF206-BT
- Physical Activity: PE 128
- Sp02, heart rate: NONIN Onyx II BT 9560 (only for chronic heart failure)
- Spirometry: Vitalograph Asma-1 (COPD only)
- Fasting Blood Glucose: AccuCheck Connect (Diabetes only)

Figure 4. Home monitoring devices and communication



It is planned to run all SENACA platforms for all countries in a cloud service located in Switzerland (SecureRack[14]). In the cloud, each country participating in the USECARE project will have its own, dedicated and isolated environment, hosting all nodes constituting a particular SENACA platform (web servers, database servers, etc.). All servers are virtualized. The cloud service level can be considered as **IaaS** (Infrastructure as a Service). Country specific Internet domains are already reserved (i.e. senaca.ch, senaca.no, senaca.il).

Figure 5. Servers and communication



Error! Reference source not found. shows two different configuration options. For the USECARE project the so-called “single host” configuration is chosen, where everything runs on a single host (web server, database server, etc.). The three types of databases that will be used are:

- ***DB Application*** – contains all SENACA applications’ core data plus interfaces to external services.
- ***DB Data*** – contains all anonymized monitored data from users, including data entered manually by user.
- ***DB Users*** – contains all necessary personal identification data of users. The user’s identifier (UUID, Universally Unique IDentifier) is used to link anonymized (i.e. de-identified) user data stored in *DB Data*. Any allocation of user data to user identification will only be effected by the user him-/herself; and identification to any third parties without user consent will be virtually and practically impossible. Access to **DB Users** is granted only for selected IP addresses and is protected by additional access credentials.

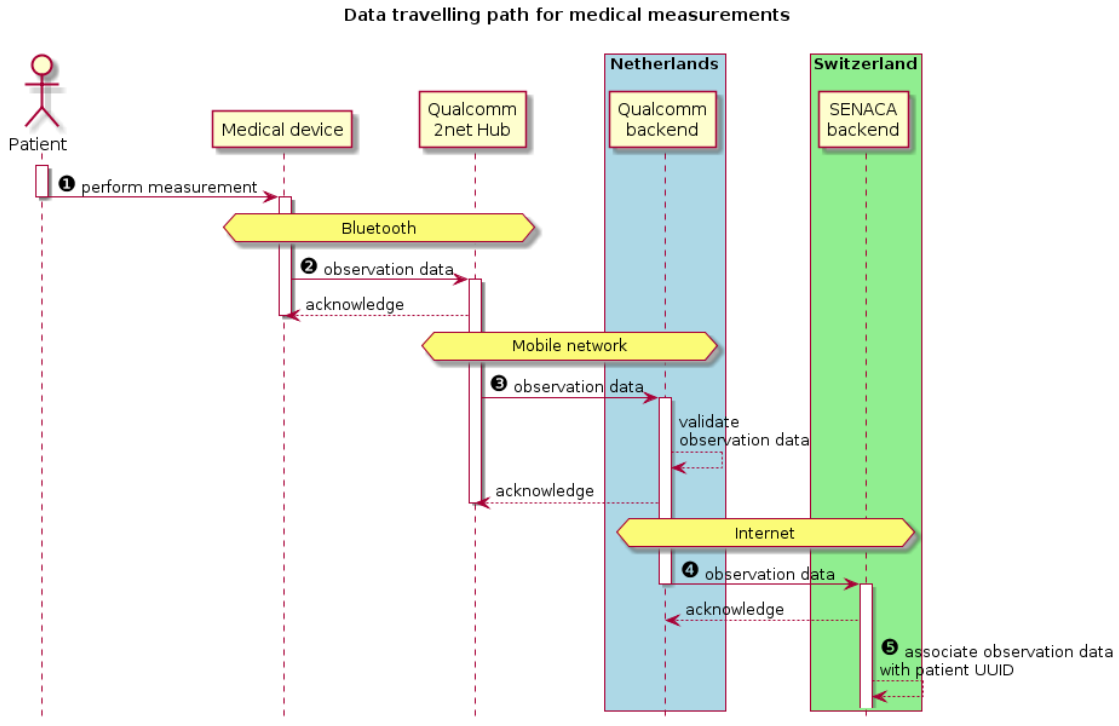
[14] https://www.securerack.com/

Locating the database *DB User* on a separate server is an option for countries participating in the USECARE project which would require this extremely high security measures. If required, this database could be hosted on an accredited high-security server by territorial partners. A service provider is considered "accredited" if several security and redundancy measures are approved, for instance physical protection of servers (only a few trusted persons can enter the service centre using strong access control mechanisms); surviving natural disasters (recovery); uninterruptible power supply; network redundancy; access control using firewalls

Error! Reference source not found. shows the measurement data flow. Measurement data from a medical device is transmitted, via Bluetooth, to the *Qualcomm 2net hub* located at the user's home. The data from medical devices are encrypted and transmitted using security protocol *SSL (Secure Socket Layer*) via a mobile service provider[15] to *Qualcomm 2net backend* located in the Netherlands. – Qualcomm[16] complies with the US HIPAA security requirements, it is listed as class 1 medical devices in US and Europe, and is compliant with ISO-13485 standards. Some detailed security clarifications from Qualcomm 2net are presented in annex 13.

The *Qualcomm 2net backend* transmits the measurement data, encrypted using security protocol SSL (Secure Socket Layer), to the particular SENACA platform were data is decrypted and persisted in *DB Data*. To keep data anonymized (de-identified), only the UUID associated with the user is assigned during this process.

Figure 6. Figure 7: Data flow diagram



❶ Patient performs a new measurement with a medical device.

[15] Orange Europe, and a Norwegian operator (TBD) cooperating with Orange
[16] http://www.qualcommlife.com/wireless-health

❷ Medical device transfers observation data to the 2net hub using Bluetooth.

❸ 2net hub transfers observation data to the Qualcomm backend system using a mobile network (SIM card).

❹ Qualcomm backend system transfers observation data to the SENACA backend system using Internet HTTPS SSL/TLS.

❺ Association of observation data with a UUID using the serial number and MAC address of the medical device used in step ❷.

As long as measurement data is 'on the wire' (steps ❷ through ❹) only the serial number and MAC address of the medical device is available to identify the measurement.

Association of observation data with a UUID (representing a particular patient) is not done until step ❺ and happens entirely inside the SENACA backend system to provide perfect patient privacy protection (no relation to a real person is exposed). In this process observation data is stored in database *Data DB* together with the UUID and is considered as de-identified. A connection to a user's real name, address, etc. can only be built using the UUID which provides the link to the user's profile data held in the separate database *User DB*.

4.3 Definition of likelihood, consequence and risk levels

Qualitative values for likelihood, consequence and risk levels are used in this risk assessment.

4.3.1 Likelihood and consequence levels

Four levels are used for identification of likelihood and four levels for identification of consequence. The levels are defined in the following tables.

The likelihood levels can be described as frequency values or with respect to how easy it is for a person to exploit a threat. For some threats it is easier to think of the likelihood in the form of frequency or a probability value. This may often be the case for threats related to availability, e.g. caused by problems in SW or HW. For other threats it is easier to think of likelihood when related to ease of misuse or mistake, or related to motivation for performing a malicious action.

For each threat or unwanted incident we choose the most appropriate column or the column that is easiest to use in order to estimate the likelihood for the threat.

Table 10: Definition of likelihood levels

Likelihood	Frequency	Ease of misuse Motivation
Very high	Very often, occurs every second use case or more, i.e. more frequently than 50 % of the time/ cases.	Can be done without any knowledge about the system; or without any additional equipment being used; or it can be performed by mistake or by wrong or careless usage.
High	Quite often. Occurs between 10 % and 50 % of the time/cases.	Can be done with minor knowledge about the system; or without any additional equipment being used; or it can be performed by wrong or careless usage.
Moderate	May happen. Occurs between 1 % and 10 % of the time/cases.	Normal knowledge about the system is sufficient; or normally available equipment can be used; or it can be performed deliberately.
Low	Rare. Occurs less than 1 % of the time/cases.	Detailed knowledge about the system is needed; or special equipment is needed; or it can only be performed deliberately and by help of internal personnel.

The consequence levels are described in terms of consequences for the patient (user) and consequences for the health service or service provider. In this case the health service or service provider is represented both by the hospital that is offering the analysed service to its patients (UNN), the underlying service provider (SENACA), and the EU project (USECARE).

For each threat or unwanted incident we choose the most appropriate description to estimate the consequence level for the threat.

Table 11: Definition of consequence levels

Consequence:	
Small	For the patient: No impact on health; or negligible economic loss which can be restored; or small reduction of reputation in the short run. For the service provider: No violation of law; or negligible economic loss which can be restored; or small reduction of reputation in the short run.
Moderate	For the patient: No direct impact on health or a minor temporary impact; or economic loss which can be restored; or small reduction of reputation caused by revealing of less serious information (e.g. blood pressure level). For the service provider: Offence, less serious violation of law which results in a warning or a command; or economic loss which can be restored; or reduction of reputation that may influence trust and respect.
Severe	For the patient: Reduced health; or a large economic loss which cannot be restored; or serious loss of reputation caused by revealing of sensitive and offending information. For the service provider: Violation of law which results in minor penalty or fine; or a large economic loss which cannot be restored; or serious loss of reputation that will influence trust and respect for a long time.

Catastrophic	For the patient: Death or permanent reduction of health; or considerable economic loss which cannot be restored; or serious loss of reputation which permanently influences life, health, and economy. For the service provider: Serious violation of law which results in penalty or fine; or considerable economic loss which cannot be restored; or serious loss of reputation which is devastating for trust and respect.

4.3.2 Acceptance criteria

We use acceptance criteria to define the acceptable risk level for the service. We cannot expect to achieve a risk level equal to zero. Thus we have to define which level of risk we consider as acceptable for the service we are analysing. The acceptance criteria should be based on the security requirements for the service.

The following acceptance criteria have been proposed for this service:

It is not acceptable that[17]:

1. (C) – the likelihood is higher than **low** that unauthorised persons (i.e. anyone else than the patients themselves and those who have a treatment relation to the patients) get access to personal health data (i.e. to sensitive data) for several patients. This is regardless of why, where, and how it happens. *(This means that in order to obtain unauthorised access to such data, detailed knowledge must be needed about the technical system, or special equipment must be needed, or it can only be performed by help of internal personnel. Or it must be more infrequent than once for every 100 use cases.)*
2. (A) – the likelihood is higher than **moderate** that the service is unavailable for a period of time. *(This corresponds to up to 4 hours of a 40 hours' work week, or that it happens not more than once for every 10 use cases.)*
3. (I) – the likelihood is higher than **low** that information provided by this service/system is being modified, or that the information presented to users can be misinterpreted and cause wrong advices and treatment. *(I.e. must be more infrequent than once for every 100 use cases.)*
4. – the likelihood that a patient dies or experience a permanent reduction of health is *higher* by the use of this service than *without* the use of this service.

4.3.3 Risk levels

We have decided to use three distinct levels for risk: *Low, Medium, and High*. Our risk level definitions are presented in Table 12.

The risk value for each threat is calculated as the product of consequence and likelihood values, illustrated in a two-dimensional matrix (Table 13). The shading of the matrix visualizes the different risk levels (the darker shading, the higher risk).

Based on the acceptance criteria, the risk level *High* is decided to be unacceptable. Any threat obtaining this risk level must be treated in order to have its risk reduced to an acceptable level.

[17] The letter in parenthesis refers to the security aspects: confidentiality (C), integrity and quality (I), availability (A)

Threats with *Low* risk level are acceptable, and *Medium* risks have to be further looked into individually.

Table 12: Definition of risk levels

Risk level:	
Low	Acceptable risk. The service can be used with the identified threats, but the threats must be observed to discover changes that could increase the risk level.
Medium	Each threat has to be investigated separately. For some threats the risk can be acceptable, but the development of the risk must be monitored on a regular basis, with a following consideration whether necessary measures have to be implemented.
High	Not acceptable risk. Cannot start using the service before risk reducing treatment has been implemented.

Table 13: Risk matrix showing the defined risk levels

Consequence: **Likelihood:**	**Small**	**Moderate**	**Severe**	**Catastrophic**
Low	Low	Low	Low	Medium
Moderate	Low	Medium	Medium	High
High	Low	Medium	High	High
Very high	Medium	High	High	High

4.4 Threat identification and analysis of risk

Threats identified in this risk assessment are listed in the threat table in Annex 14. For each possible threat we evaluated its impact or consequence and the likelihood that it would occur. Threats were given qualitative values for consequence and likelihood, according to definitions in tables 12 and 13.

A total of 29 possible threats were identified to the USECARE service at UNN. The threats are placed in the risk matrix (see table below) according to their likelihood and consequence values. Threats are uniquely identified by a combination of letters and numbers, where the letters indicate which of the information security aspects confidentiality (c), integrity (i), or availability (a) the threat is related to.

For four of these threats it turned out to be difficult to analyse their likelihood at the current stage: Three of the threats (c8, i13, i14) relate to the use of a mobile application for accessing the stored information. Currently, we have not enough information about this app to evaluate these threats. Another of the threats (i9) refers to the possibility for the user to make mistakes in the user interface of the web client. It is difficult to analyse the likelihood for this without any experience from users of the service. These four threats are therefore not placed in the risk matrix.

Table 14: Risk matrix for the USECARE service at UNN

Consequence: Likelihood:	Small	Moderate	Severe	Catastrophic
Low	c2, c7, i1, i2, i3, i4, i5, i6, i7, i8, i10, i12, a4, a5, a6, a7	c4, c5 a1, a2	c3 *(c2, i1, i2, i3, i4, i5, i6, i7, i8, i10, i12, a1, a2, a4, a5, a6, a7)*	
Moderate	i11	c6 a3		
High	c1			
Very high				

As can be seen from the risk matrix, none of the analysed threats were given an unacceptable *high* risk level. A large number of the threats were analysed as *low* risk for the users, but as *medium* risk for the service: its reputation, and the users' motivation to use the service. (These threats are included twice in the matrix, in parenthesis for the *medium* risk case.) Threats with *medium* risk level must be analysed in more detail, and they can end up being acceptable or unacceptable, while threats with *low* risk are basically acceptable.

4.4.1 Confidentiality threats

This section describes threats concerning unauthorised access to sensitive information. According to both Norwegian and European legislation, health information is sensitive if it can be linked to an identifiable person (see chapter **Error! Reference source not found.**). In this service, the health information is *de-identified*, not fully anonymised. With access to DB Users (see **Error! Reference source not found.**), health information in DB Data can be identified by the UUID.

Two of the eight confidentiality threats have got *medium* risk level:

Threat c3 – the possibility for unauthorized access to sensitive data by deliberate attack on the SENACA servers in Switzerland or the Qualcomm backend servers in the Netherlands. By "deliberate", the attacker is assumed to be a person who wants to find this particular information. If this happens, the consequence is considered as *severe*, both because it is a breach to the privacy of that patient and, even more, for the trust in and reputation of the service. The likelihood is, however, assessed as very *low*: First, it is difficult to see any motivation for this to happen. Next, the information in Qualcomm backend is without the UUID, and in the SENACA servers, the attacker will need access to the UUID in the DB Users as well as to the data in DB Data. – This *medium* risk is therefore considered acceptable.

Threat c6 – the possibility that unauthorized persons can log in to the user's account (web site) and read sensitive information for that patient. The authentication mechanism is password only. Password restrictions are not known. – If the password is simple, it may be easy to guess; if the password is difficult, it may be written down. In addition, the web client allows username and password to be stored/remembered. Even if it can be done very easily, the likelihood that someone really will use this opportunity to log into the user's web-account is considered

moderate. The consequence is assessed as *moderate*, it is information only about this/one patient that is revealed.
– The risk can be acceptable for the use in this project. *However, it is strongly recommended to improve the authentication mechanism, both by avoiding the possibility to store/remember login credentials, and by adding a second factor to the authentication, e.g. a one-time password sent via mobile phone (SMS) to the legitimate user.*

In addition, there is one confidentiality threat among those which were analysed as *low* risk for the users, but as *medium* risk for the service:

Threat c2 – this is the same case as threat c3 above, but in this case the attack is from casual external persons. There are mainly two types of such "hackers": 1. "Scriptkiddies" who want to prove what they are able to do; and 2. Persons who want to obtain money (sell data, or use it for blackmailing). The likelihood is assumed to be *low*, but it depends on the security measures at the SENACA operating centre (where both databases have to be attacked). Security measures should be described in a "Data processing agreement". The consequence is considered *small* for the patient, as a casual "hacker" is not expected to know the patient. The risk is therefore acceptable. But the consequence is worse (*severe*) for the service and service provider's reputation, and the users' trust in and motivation to use the service.

The remaining confidentiality threats (c1, c4, c5, c7) have *low* risk level. These threats are related to possible unauthorised access by administrators and operators at the two centres (**c1**), and to possible unauthorised access to data during transfer via bluetooth (**c7**), mobile network (**c5**) or internet (**c4**).

4.4.2 Integrity threats

This section describes threats concerning unauthorised modification of information and threats to the information's accuracy, correctness, and completeness. If these data were meant to be used for changes in treatment or medication for the patient, the consequence of wrong information could, in worst case, be very serious. But that is not the purpose of the information in this service. The stored data can be checked by the users themselves, and in in case of strange values, the patient should be called-in for a thorough control by the clinicians.

Most of the integrity threats are among those which were analysed as *low* risk for the users, but as *medium* risk for the service and service provider's reputation, and the users' trust in and motivation to use the service. In all cases, the risk is considered acceptable. These are the threats:

Threats i1-i4 are related to possible modification of data stored in the servers, either in the Qualcomm backend or in the SENACA servers. Modification could be caused, accidentally or deliberately, by administrators or operators in the operating environment, or by external attackers.

Threats i5, i6, i7 and i10 refer to possible modification of data during transfer, either in the bluetooth transfer in the patient's home (**i10**), in the mobile network between the hub in the patient's home and the Qualcomm backend (**i6**), or in internet between Qualcomm backend and SENACA servers (**i5**). The modifications could be caused by deliberate attacks to the transfer medium, or be caused by software errors (**i7**).

Threats i8 and i12 – the possibility that unauthorized persons can log in to the user's account on the web site (**i8**) or via the mobile application (**i12**) and modify the user's information. Authentication mechanisms and password policy for the web interface, seem too weak. Authentication mechanisms for the mobile app is unknown at this point. – Even if these risks can be acceptable for the use in this project, it is strongly recommended to improve the authentication mechanism, as discussed for threat c6 above.

The last integrity threat (**i11**) has *low* risk level. This threat refers to the possibility that fake/false values are registered for the user because unauthorized persons, e.g. children, "play" with the monitoring equipment. The likelihood may be *moderate*; it depends on who are around and can get hold of the monitoring devices. There are also other uncertainties/questions related to this:

- Will measurements be transferred immediately ("always on")?
- Is it possible for the user to delete their own registrations, e.g. if they discover a false registration?
- Is it possible for the user to insert comments to their own registrations?

The consequence is, however, considered *small* for the patient: data and information can be checked, and it will not be used for change of treatment or medication.

4.4.3 Availability threats

This section describes threats concerning information being accessible and usable upon demand by authorized users.

One of the seven availability threats have got *medium* risk level:

Threat a3 – the possibility that users cannot log in to their web account because of problems with their own private devices (PC, tablet, mobile phone). This may very well happen, the likelihood is set to *moderate*, but it also depends on the users' computer literacy. The consequence is considered *moderate*, mainly because the users may be demotivated if they do not get help to solve such problems. This is more of a private problem for each user, and the risk is considered acceptable.

The rest of the availability threats are among those which were analysed as *low* risk for the users, but as *medium* risk for the service and service provider's reputation, and the users' trust in and motivation to use the service. It depends how long these types of problem last. In all cases, the risk is considered acceptable. These are the threats:

Threats a1 and a2 – the possibility that users cannot log in to their web account because of problems with the SENACA servers (**a1**) or because of network problems (**a2**). The likelihood is set to *low*: We assume that the service providers (Qualcomm, SENACA) are professional organisations with stable systems and quick fix of problems, and the network connections, both mobile network and internet, are also experienced as stable (when existing). As for threat a3 above, the consequence is considered *moderate* for the patient. The consequence is worse (*severe*) for the service and service provider.

Threats a4-a7 refer to the problem that monitoring data from the user are not being transferred to the servers. This can be caused by different types of server problems (**a4**), network problems at any level (**a5**), problems at the local access point (hub/aggregator) in the patient's home

(**a6**), or problems with the monitoring equipment itself (**a7**). The likelihood is considered *low* in all cases. Regarding the monitoring devices and the hub, we assume this is a stable and well tested technology. The consequence is considered *small* for the patient, but worse (*severe*) for the service and service provider.

4.5 Recommended risk treatment

There are basically four different approaches to handle a risk:

1. **Accept** the risk, in accordance with the organisation's security policy. This approach is usually applied for the risks with an acceptable risk level. *It is worth remembering that accepting the risk does not mean accepting the unwanted incident indicated by the threat.*
2. **Reduce** the risk to an acceptable level. Since the risk is a product of likelihood and consequence, this means to reduce the likelihood, the consequence, or both. It is often difficult to reduce the consequence of a threat, so the focus should first of all be on reduction of the likelihood.
3. **Avoid** the risk, i.e. try not to be exposed to the risk, not do the things that could lead to the risk.
4. **Transfer** the risk to a third party (e.g. an insurance company)

In our analysis we mainly stick to strategies 1 and 2 above and recommend security measures that can *reduce risks*. Risk reduction should be subject to a cost/benefit analysis. Some measures can reduce the risk level for several threats at the same time, and simple and cost-effective measures that can reduce even an acceptable risk, should preferably be implemented.

As can be seen from the analysis in section 4.4, no threats were assessed to have unacceptable risk. Three threats were analysed to have *medium* risk, in addition to a large number of threats which were analysed as *low* risk for the users, but as *medium* risk for the service: its reputation, and the users' trust in and motivation to use the service.

Threat c6 is the threat closest to not being accepted: The authentication mechanism is password only for login to the user's account (web site). It makes it too easy for unauthorized persons to log in and read sensitive information for that patient. In addition, the web client allows username and password to be stored/remembered. – For this limited project, however, the risk for unauthorized access has been accepted, based on the thought that no one will use this opportunity to log into the user's web-account, no one is really interested in reading these values.

According to Norwegian regulations in Code of conduct for information security[18], authentication for access to health information via web sites requires use of personal qualified certificate, i.e. security level 4 – or another solution "that based on a risk assessment is considered good enough". For this service we would strongly recommend at least security level

[18] The Norwegian Directorate of eHealth (NDE): Code of Conduct for information security in the healthcare and care services. https://ehelse.no/personvern-og-informasjonssikkerhet/norm-for-informasjonssikkerhet/documents-in-english

3 for access to the user's account, e.g. a one-time password sent via SMS, in addition to username and password.

Acceptable threats with *medium* risk could preferably be treated, and several of the proposed measures will also help to keep a *low* risk on the remaining threats.

The table below gives an overview of possible security measures and indicates the threats which can have the risk reduced by these measures. These measures will then contribute to reduction of the total risk for the system.

Table 15: Recommended security measures

Security measures	Related threats
Security training and privacy awareness:	
• Keep login credentials (password, PIN) secret	c6, c8, i8, i12
• Training/education in use of the service	a3, a5
• Check the data stored on the SENACA servers (Is it the same as registered by the monitoring devices?)	i1, i2, i3, i4, i5, i6, i7, i8, i11
• Keep the monitoring devices away from children or other persons who want to "play"/tamper with it	i11
Routines and procedures:	
• Data processing agreement between UNN and SENACA	c1, c2, i1, i2, i3
• Define requirements for password strength	c6, i8
• Notify users about known unavailability periods	a1, a4, a6
• Helpdesk or contact information for support	a1, a2, a3, a7
Software and configuration:	
• Remove possibility to store/remember login credentials for web account	c6, i8
• Strengthen the authentication mechanism, e.g. by use of an additional one-time password	c6, c8, i8, i12
• Possibility for users to comment on registrations from monitoring equipment	c11

In addition, some technical security measures are already built in to the system (see chapter 4.2 and Annex 13):

- User data and medical data stored in different databases.
- Encrypted transfer of data. End-to-end encryption between Qualcomm hub in patient's home and the Qualcomm backend (AES 128 bits)
- Qualcomm backend system transfers observation data to the SENACA servers using Internet HTTPS SSL/TLS.
- SSL/TLS encryption (HTTPS) for web access to stored data
- Remote update of hub software

4.6 Conclusion

This report documents the risk assessment of privacy and information security aspects of the Norwegian field-test of the EU-funded project USECARE. The risk assessment was conducted in the November and December 2015 and January 2016.

A total of 29 possible threats were identified. These are listed in the threat table in Annex 14. The result of the analysis (chapter 4.4) shows that no threats were assessed to have unacceptable risk. Three threats were analysed to have *medium* risk, in addition to a large number of threats which were analysed as *low* risk for the users, but as *medium* risk for the service: its reputation, and the users' trust in and motivation to use the service.

Regarding the confidentiality aspect, there are two places where the person identifiable health information (i.e. sensitive information) can be revealed:

- By logging in via a user's account – threats c6 (web) and c8 (mobile app)
- At the SENACA servers, where administrators and operators (threat c1) and external attackers (threats c2 and c3) can access both DB Users and DB data.

Threat c6 is the threat closest to not being accepted (see also chapter 5).

Some necessary and useful security measures are proposed in section 4.5, also measures against threats which have an acceptable risk level. By reducing risk for threats which are individually acceptable, the total risk level for the system will be reduced. It is therefore recommended that as many as possible of the proposed measures are being implemented.

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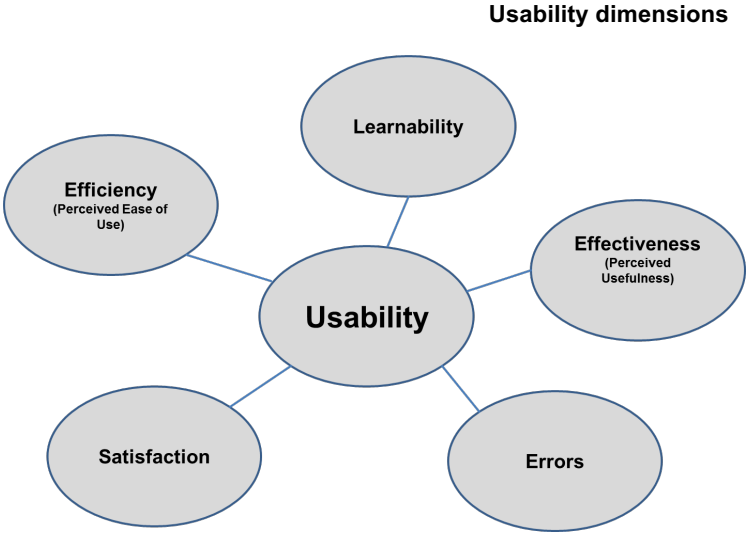
6 Annexes

6.1 Annex 1 – Additional information on measurements

Part I – preliminary studies: usability

Usability of the enhanced SENACA prototype will be evaluated during the implementation in view of user's expected perceived usability and user's experienced perceived usability (see Figure 3). Both will be assessed using the three subscales of the TAM measuring perceived usefulness (PU), perceived ease of use (PEOU) and intention to use at the three time points (T_1-T_3) (see annex 2a). Furthermore the items of the PSSUQ will be applied (see annex 2b). The TAM is considered a valid and robust model (45). In sum, it consists of a 9-item instrument evaluating four statements on the main determinants of intention to use (PU and PEOU) and one on the planned behaviour respectively the intention to use (IU). While statements on perceived ease of use refer more to the aspect of effortlessness in using ICT applications, statements on perceived usefulness refer rather to perceived benefits gained by the use of technology (see theoretical notes in background section). All subscales are rated on a 7-point Likert-scale (1 = 'extremely unlikely' to 7 = 'extremely likely') (see annex 2a). The TAM measures are brief and easy to use and have good reliability (Cronbach's alpha ranging from 0.82 to 0.98) and good convergent validity (> 0.6) (44,52).The wording of the items will slightly be modified in order to fit the setting of USECARE AAL. Two separate versions will be developed to apply to the pre- and post-implementation periods. In addition, items from Technology Readiness Index will be included to predict technology acceptance or rather perceived ease of use and perceived usefulness on the individual level (25,53,54) (see annex 2c).



The usability parameters will also include the percentage of approached potential users not willing to participate, the attrition rate (number of participants discontinuing with the program during the intervention period), the participants' performance (e.g. completion of self-management tasks) and the percentage of days / households without malfunctioning of the system (devices and website) (see annex 6).

Part II – pre-experimental design: Quality of life (QoL), health-related behaviour and clinical parameters

A main study parameter is **QoL**, which will be assessed using the EQ-5D (the EuroQol 5-dimension inventory) as a generic standardised measure of health status with low respondent burden that provides a cognitively simple, generic measure of health for clinical and economic appraisal (55). The EQ-5D system consists of a self-classifier descriptive system with five dimensions (mobility, self-care, usual activities, pain / discomfort, and anxiety / depression), with each dimension described at five response levels, roughly corresponding to having no, slight, moderate, severe, and extreme problems. The EQ-5D-5L also includes a vertical visual analogue scale (VAS) to enable respondents to provide a self-rating of his or her own health (endpoints with ”0“ labelled “worst imaginable health” and “100” labelled “best imaginable health”). Although the EQ-5D-5L has been primarily designed as pen-and-paper self-complete instrument, it is available in alternative formats and modes of administration, i.e. for tablet, web or telephone. The EQ-5D-5L and the EQ-5D VAS will be administered at baseline, after 50 days, and along with the final clinical assessment through the web-site interface. Participants will have the option to use the EQ-5D-5L biweekly for voluntary self-monitoring of their quality of life.

6.2 Annex 2a – Technology Acceptance Model (TAM)

Please indicate your level of agreement with each of the following statements using the scale provided below.

Remember to **select a single option** for each statement.

-3	-2	-1	0	+1	+2	+3
Totally disagree	Disagree	Slightly disagree	Neither agree nor disagree	Slightly agree	Agree	Totally agree

1. My interaction with SENACA was clear and understandable	-3 ☐	-2 ☐	-1 ☐	0 ☐	+1 ☐	+2 ☐	+3 ☐
2. Interacting with SENACA did not require a lot of mental effort	-3 ☐	-2 ☐	-1 ☐	0 ☐	+1 ☐	+2 ☐	+3 ☐
3. I found SENACA easy to use	-3 ☐	-2 ☐	-1 ☐	0 ☐	+1 ☐	+2 ☐	+3 ☐
4. I found it easy to get SENACA to do what I wanted it to do	-3 ☐	-2 ☐	-1 ☐	0 ☐	+1 ☐	+2 ☐	+3 ☐
5. Using SENACA improved my performance in monitoring my health	-3 ☐	-2 ☐	-1 ☐	0 ☐	+1 ☐	+2 ☐	+3 ☐
6. Using SENACA in health monitoring processes increased my productivity	-3 ☐	-2 ☐	-1 ☐	0 ☐	+1 ☐	+2 ☐	+3 ☐
7. Using SENACA enhanced my effectiveness in monitoring my health	-3 ☐	-2 ☐	-1 ☐	0 ☐	+1 ☐	+2 ☐	+3 ☐
8. I found SENACA to be useful to monitor my health	-3 ☐	-2 ☐	-1 ☐	0 ☐	+1 ☐	+2 ☐	+3 ☐
9. Given that I had access to SENACA after the study I intend to use it in the future	-3 ☐	-2 ☐	-1 ☐	0 ☐	+1 ☐	+2 ☐	+3 ☐

6.3 Annex 2b – Post-Study System Usability Questionnaire (PSSUQ)

Please indicate your level of agreement with each of the following statements using the scale provided below. Remember to **select a single option** for each statement.

	-3	-2	-1	0	+1	+2	+3
1. Overall, I am satisfied with the system	☐	☐	☐	☐	☐	☐	☐
2. Overall, I am satisfied with how easy it was to use the system	☐	☐	☐	☐	☐	☐	☐
3. It is simple to use the system	☐	☐	☐	☐	☐	☐	☐
4. I can effectively manage my health by using the system	☐	☐	☐	☐	☐	☐	☐
5. I am able to manage my health quickly using the system	☐	☐	☐	☐	☐	☐	☐
6. I am able to efficiently manage my health using the system	☐	☐	☐	☐	☐	☐	☐
7. I feel comfortable using the system	☐	☐	☐	☐	☐	☐	☐
8. It was easy to learn to use the system	☐	☐	☐	☐	☐	☐	☐
9. The system gave error messages that clearly told me how to fix problems	☐	☐	☐	☐	☐	☐	☐
10. Whenever I made a mistake using the system, I could recover easily and quickly	☐	☐	☐	☐	☐	☐	☐
11. The information provided for the system is easy to understand	☐	☐	☐	☐	☐	☐	☐
12. The information provided with the system (online help, documentation) is clear	☐	☐	☐	☐	☐	☐	☐
13. It is easy to find the information I need	☐	☐	☐	☐	☐	☐	☐
14. The information is effective in helping me managing my health.	☐	☐	☐	☐	☐	☐	☐
15. The system has all the functions and capabilities I expect it to have	☐	☐	☐	☐	☐	☐	☐
16. I like using the interface of the system *Note: The interface includes those items that you use to interact with SENACA such as the screens, graphs and language.*	☐	☐	☐	☐	☐	☐	☐

17. The organization of information on the system's screens is clear	-3 ☐	-2 ☐	-1 ☐	0 ☐	+1 ☐	+2 ☐	+3 ☐
18. The interface of the system is pleasant	-3 ☐	-2 ☐	-1 ☐	0 ☐	+1 ☐	+2 ☐	+3 ☐

6.4 Annex 2c – Technology Readiness Index (TRI)

Please indicate how much you agree with the following statements.

	Strongly disagree	Somewhat disagree	Neutral	Somewhat agree	Strongly agree
1. New technologies contribute to a better quality of life	☐	☐	☐	☐	☐
2. Technology gives me more freedom of mobility	☐	☐	☐	☐	☐
B. Technology gives people more control over their daily lives	☐	☐	☐	☐	☐
B. Technology makes me more productive in my personal life	☐	☐	☐	☐	☐

	Strongly disagree	Somewhat disagree	Neutral	Somewhat agree	Strongly agree
B. Other people come to me for advice on new technologies	☐	☐	☐	☐	☐
B. In general, I am among the first in my circle of friends to acquire new technology when it appears	☐	☐	☐	☐	☐
B. I can usually figure out new high-tech products and services without help from others	☐	☐	☐	☐	☐
B. I keep up with the latest technological developments in my areas of interest	☐	☐	☐	☐	☐

	Strongly disagree	Somewhat disagree	Neutral	Somewhat agree	Strongly agree
9. When I get technical support from a provider of a high-tech product or service, I sometimes feel as if I am being taken advantage of by someone who knows more than I do	☐	☐	☐	☐	☐

10. Technical support lines are not helpful because they don't explain things in terms I understand	☐	☐	☐	☐	☐
11. Sometimes, I think that technology systems are not designed for use by ordinary people	☐	☐	☐	☐	☐
12. There is no such thing as a manual for a high-tech product or service that's written in plain language	☐	☐	☐	☐	☐

TRI (cont.)

	Strongly disagree	Somewhat disagree	Neutral	Somewhat agree	Strongly agree
13. People are too dependent on technology to do things for them	☐	☐	☐	☐	☐
14. Too much technology distracts people to a point that is harmful	☐	☐	☐	☐	☐
15. Technology lowers the quality of relationships by reducing personal interaction	☐	☐	☐	☐	☐
16. I do not feel confident doing business with a place that can only be reached online	☐	☐	☐	☐	☐

6.5 Annex 2d – eHealth Literacy (eHEALS)

Please indicate your level of agreement with each of the following statements using the scale provided below.

Please select a single option for each statement

-2 **Strongly disagree**	**-1** Somewhat disagree	0 Neutral	+1 Somewhat agree	**+2** **Strongly agree**

	-2	-1	0	+1	+2
1. I know how to find helpful health resources on the Internet	☐	☐	☐	☐	☐
2. I know how to use the Internet to answer my health questions	☐	☐	☐	☐	☐
3. I know what health resources are available on the internet	☐	☐	☐	☐	☐
4. I know where to find helpful health resources on the internet	☐	☐	☐	☐	☐
5. I know how to use the health information I find on the Internet to help me	☐	☐	☐	☐	☐
6. I have the skills I need to evaluate the health resources I find on the Internet	☐	☐	☐	☐	☐
7. I can tell high quality from low quality health resources on the Internet	☐	☐	☐	☐	☐
8. I feel confident in using information from the Internet to make health decisions	☐	☐	☐	☐	☐

6.6 Annex 3 – EQ5D-5L (UK English sample version)

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

I have no problems in walking about	❑
I have slight problems in walking about	❑
I have moderate problems in walking about	❑
I have severe problems in walking about	❑
I am unable to walk about	❑

SELF-CARE

I have no problems washing or dressing myself	❑
I have slight problems washing or dressing myself	❑
I have moderate problems washing or dressing myself	❑
I have severe problems washing or dressing myself	❑
I am unable to wash or dress myself	❑

USUAL ACTIVITIES (*e.g. work, study, housework, family or leisure activities)*

I have no problems doing my usual activities	❑
I have slight problems doing my usual activities	❑
I have moderate problems doing my usual activities	❑
I have severe problems doing my usual activities	❑
I unable to do my usual activities	❑

PAIN / DISCOMFORT

I have no pain or discomfort	❑
I have slight pain or discomfort	❑
I have moderate pain or discomfort	❑
I have severe pain or discomfort	❑
I have extreme pain or discomfort	❑

ANXIETY / DEPRESSION

I am not anxious or depressed	❑
I am slightly anxious or depressed	❑
I am moderately anxious or depressed	❑
I am severely anxious or depressed	❑
I am extremely anxious or depressed	❑

(EQ5D-5L, cont.)

- We would like to know how good or bad your health is TODAY.

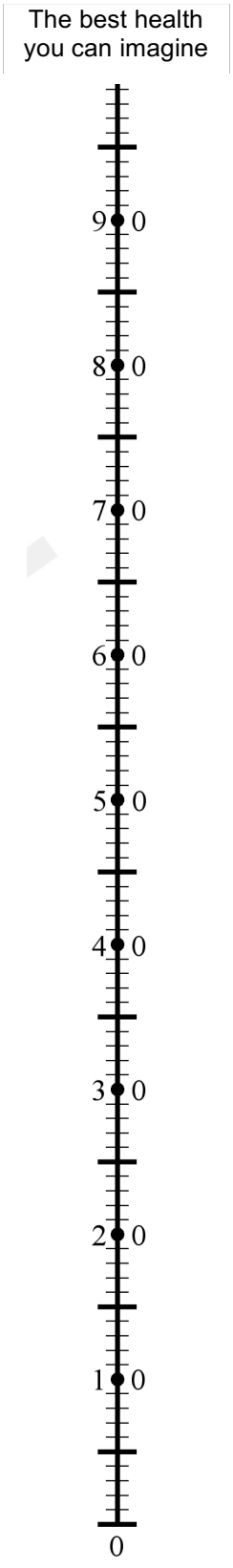
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.

  0 means the worst health you can imagine.

- Mark an X on the scale to indicate how your health is TODAY.

- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐



6.7 Annex 4 – Health-related behaviour

The questions related to health-related behaviour originate from different scales (e.g. Stanford research instruments) and are slightly modified in order to fit to the study setting and population.

1: Do you smoke cigarettes?

(Please tick one box only)

- ☐ Yes, I do → go to question **I2**
- ☐ No, I never did
- ☐ No, I don't but I did in the past

➔ When did you stop smoking? Month: __.__ Year: __.__.__.__

2: How many cigarettes on average do you smoke per day?

(Please fill in your average daily cigarette consumption)

On average, I smoke _____ cigarettes per day

3: Do you currently use any of the following tobacco or nicotine products; chewing tobacco or snuff, cigars, tobacco pipes, clove cigarettes or bidis, e-cigarettes, nicotine replacement products such as gum or patch or any other tobacco products besides cigarettes?

(Please tick each box that applies to you)

- ☐ Yes, I chew or snuff tobacco
- ☐ Yes, I smoke cigars
- ☐ Yes, I smoke tobacco pipes
- ☐ Yes, I smoke clove cigarettes or bidis
- ☐ Yes, I smoke e-cigarettes
- ☐ Yes, I use nicotine replacement products
- ☐ Other: _____
- ☐ No

4: Please think about a normal week. How many units of alcohol do you drink per week (one unit corresponds to 1 beer, 1 glass of wine or 4cl. of spirits)?

(Please fill in the number of units)

_____ units per week

5: Please think about a normal week. How many portions of vegetables do you eat per week?

Vegetables are all cooked and uncooked vegetables; salads; and boiled, baked and mashed potatoes. Do not count French fries or chips.

One portion is 80g of vegetables corresponding to e.g. two broccoli spears, one medium tomato, three heaped tablespoons of beans or carrots, etc.)

(Please fill in the number of portions)

_____ portions per week

6: Please think about a normal week. How many portions of fruits do you eat per week?

Include fresh, frozen or canned fruits.

One portion is 80g of fruit corresponding to e.g. two plums, seven strawberries, one apple, one slice of pineapple, etc.) (Please fill in the number of portions)

_____ portions per week

7: During the past week (even if it was not a typical week for you), how much total time (for the entire week) did you spend on each of the following activities?

(Please make one cross on each line)

How much time during the past week…	**None**	**Less than 30 minutes / week**	**30-59 minutes / week**	**1-3 hours / week**	**More than 3 hours / week**
Stretching or strengthening exercises (range of motion, weights, etc.)					
Walk for exercise, hiking, Nordic walking					
Swimming or aquatic exercise					
Bicycling (including stationary exercise bikes)					
Other aerobic exercise equipment (stairmaster, rowing skiing machine, etc.)					
Other aerobic exercise: Please specify: _____					

8: Do you walk outside?

(with walking outside we mean walking to go shopping or doing other daily activities like visiting someone; we do not mean: a walking tour; Please tick one box only).

☐ No → go to question **I11**

☐ Yes

9: How many times did you walk during the past two weeks?

(with walking outside we mean walking to go shopping or doing other daily activities like visiting someone; we do not mean: a walking tour; Please fill in the correct number).

I walked |__||__| times in the past two weeks

10: How long did you usually walk each time?

(with walking outside we mean walking to go shopping or doing other daily activities like visiting someone; we do not mean: a walking tour; Please fill in the correct number).

I usually walk |__||__| hours and |__||__| minutes

11: Please think about the past two weeks. Did your overall activity level change as compared to the rest of the year? (Please tick one box only)

- ☐ No, my activities did not change at all.
- ☐ Yes, I am more physically active than before.
- ☐ Yes, I am less physically active than before.
- ☐ I don't know

6.8 Annex 5 – Self-Efficacy

For each of the following questions, please choose the number that corresponds to your confidence that you can do the tasks regularly at the present time.

(Please select a single option for each statement)

1: How confident are you that you can keep the fatigue caused by your disease from interfering with the things you want to do?

Not at all confident	1	2	3	4	5	6	7	8	9	10	Totally confident

2: How confident are you that you can keep the physical discomfort or pain of your disease from interfering with the things you want to do?

Not at all confident	1	2	3	4	5	6	7	8	9	10	Totally confident

3: How confident are you that you can keep the emotional distress caused by your disease from interfering with the things you want to do?

Not at all confident	1	2	3	4	5	6	7	8	9	10	Totally confident

4: How confident are you that you can keep any other symptoms or health problems you have from interfering with the things you want to do?

Not at all confident	1	2	3	4	5	6	7	8	9	10	Totally confident

5: How confident are you that you can do the different tasks and activities needed to manage your health condition so as to reduce your need to see a doctor?

Not at all confident	1	2	3	4	5	6	7	8	9	10	Totally confident

6: How confident are you that you can do things other than just taking medication to reduce how much your illness affects your everyday life?

Not at all confident	1	2	3	4	5	6	7	8	9	10	Totally confident

6.9 Annex 6 – Adherence to SENACA and actual use of SENACA

1: Did you start using SENACA?

(Please tick one box only)

- ☐ Yes → go to question T2
- ☐ No → if no: Why did you not start using SENACA?

Reason(s): _____

_____

_____

→ go to Question C1

2: When did you start using SENACA after receiving it?

(Please tick one box only)

- ☐ **immediately** after receiving it
- ☐ in the **first week** after receiving it
- ☐ in the **second week** after receiving it
- ☐ in the **third week** after receiving it
- ☐ **later** than the third week after receiving it

3a: Has there been a time when you stopped using SENACA?

(Please tick one box only)

- ☐ No → go to question **T4**
- ☐ Yes → if yes: Why did you stop using SENACA?

Reason(s): _____

_____

3b: If yes: For how many days did you approximately stop using SENACA?

(Please fill in the correct number)

I stopped using SENACA in total for |__| |__| days.

4: During the period you used SENACA, how often did you use at least one function of the system? (Please tick one box only)

- ☐ More than once per day
- ☐ Daily
- ☐ Twice to six times per week
- ☐ Once a week
- ☐ Two to three times per month
- ☐ Once per month

☁ Less often

5: During the period you used SENACA, how many <u>hours per week</u> did you spend using SENACA on average?

(Please fill in the average number of hours per week)

On average, I used SENACA |___| |___| hours per week.

6: Below you find a list with the several <u>elements</u> of SENACA. Which elements did you use? And how many times per week?

(Please mark every element you used and fill in how often you used it on average per week)

Type of element

☁	Personal health plan	|___| |___| times per week.
☁	Personal health statistics	|___| |___| times per week.
☁	Recipes & Nutrition information	|___| |___| times per week.
☁	Physical activity tutorials	|___| |___| times per week.
☁	Disease specific information pages	|___| |___| times per week.

7: Below you find a list with the several monitoring <u>devices</u> included in SENACA. Which devices did you use? And how many times per week?

(Please mark every device you used and fill in how often you used it on average per week)

Monitoring devices

☁	Blood pressure	|___| |___| times per week.		
☁	Weight scale	|___| |___| times per week.		
☁	Physical activity tracker	|___| |___| times per week.		
☁	Vitalograph	|___| |___| times per week.	☁	not applicable
☁	Glucose measure	|___| |___| times per week.	☁	not applicable

8: Did you have any problems related to SENACA during the last 50 days?

☐ **No** ☐ **Yes, namely:** _____

→go to question C1

_____

_____

_____

9: If yes: How often did those problems occur? Please tell us the approximate occurrence in the last 50 days.

Problem: _____ Average occurrence last 50 days: _____

Problem: _____ Average occurrence last 50 days: _____

Problem: _____ Average occurrence last 50 days: _____

Problem: _____ Average occurrence last 50 days: _____

Only for drop-outs:

10: Could you tell us the main reasons why you decided to stop participating in the study?

_____

_____

_____

_____

_____

_____

_____

0.

6.10 Annex 7a – Socio-demographics (patient)

1. What is your gender?

☐ **Male** ☐ **Female**

2. Which year were you born?

3. (Please enter the two last numbers of your year of birth)

4.

5. |1| |9| |__||__|

3: In which country do you live?

(Please tick one box only)

- ☐ Switzerland
- ☐ Norway
- ☐ Israel
- ☐ Other: _____

4: Is the language mostly spoken in this country your mother tongue?

(Please tick one box only)

- ☐ Yes
- ☐ No

5: What is your current marital status?

(Please tick one box only)

- ☐ Married / Civil Partnership
- ☐ Separated / Divorced from spouse or civil partner
- ☐ Widowed/ civil partner died
- ☐ Never married/ never in a civil partnership, single

6: Do you live alone?

(Please tick one box only)

- ☐ Yes → go to question **7**

- No → if no: Please tell us how many persons you are living with including yourself:

Total household size: ____ persons

Please fill in the table below by indicating the relationship to the persons you are living with, e.g. "Person n°1: Husband; Person n°2: Daughter, …"

Person Number	Relationship

7: Which person do you consider as the most important caregiver? If the person lives in your household, please enter the number of the person from the table above.

(Please tick one box only)

- Person lives in household: Number |__|
- Somebody who does not live in my household

8: How many full years of schooling do you have? Please include primary and secondary schooling, university and full-time vocational training, but do not include repeated years.

(Please enter the total number of years)

|__||__| Years

9: What is the highest level of education that you have attained?

(Please tick one box only)

- No formal education
- Primary school
- Lower Secondary (end of obligatory school; does not allow entry to university)
- Upper Secondary (allow entry to university)
- Post-Secondary, non-tertiary (vocational training)
- Lower level tertiary (Bachelor degree, also technical schools)

- Upper level tertiary (Diploma, Magister, Master degree, doctor)

10: What is your current work status?

(Please tick one box only)

- Employed
- Unemployed
- Self-employed
- Student/ scholar
- Retired
- Houseman/-wife
- Unable to work due to illness
- Other: _____

6. (Please enter the total number of years)

7.

8. |__||__| Years

9.

10.

11: Which of the following three chronic diseases do you have?

(Please tick each box that applies to you)

- Heart disease (chronic heart failure)
- Diabetes (Diabetes mellitus)
- Lung disease (chronic obstructive pulmonary disease)

12: Since how many years and months is this disease diagnosed?

(Please enter the exact number of years and months. If you don't remember the exact number please try to estimate. If you have ticked more than one box in E1, please refer to the disease that was diagnosed first)

Years **|__||__|** Months **|__||__|**

13: Did you have hip and/or knee replacement?

(Please tick one box only)

- No
- Yes

14: If you had hip or knee replacement, how many days passed by since that surgery?

(Please enter the exact number of days. If you don't know the exact number please try to estimate)

Days |__||__|

- ☁ No hip/ knee replacement

15: Apart from the diseases you reported in the questions before, which other diseases do you have?

(Please tick each box that applies to you)

- ☁ Cancer
- ☁ Mental disease
- ☁ Musculoskeletal diseases (Rheumatism, Osteoporosis, Arthritis, Spinal cord, back pain)
- ☁ Asthma
- ☁ Fibromyalgia
- ☁ Severe allergy
- ☁ Multiple sclerosis
- ☁ Neurological disease (incl. Parkinson's and dementia)
- ☁ Hypertension
- ☁ Emphysema
- ☁ Gastrointestinal diseases (incl. Crohn's disease)
- ☁ Other _____

6.11 Annex 7b – Socio-demographics (caregiver)

1: What is your gender?

(Please tick one box only)

☁ Male ☁ Female

2: Which year were you born?

(Please enter the two last numbers of your year of birth)

|1| |9|__||__|

3: In which country do you live?

(Please tick one box only)

- ☁ Switzerland
- ☁ Norway
- ☁ Israel
- ☁ Other: _____

4: What is your current work status regarding the main amount of hours you spend on?

(Please tick one box only)

- ☁ Employed
- ☁ Unemployed
- ☁ Self-employed
- ☁ Student/ scholar
- ☁ Retired
- ☁ Houseman/-wife
- ☁ Unable to work due to illness or accident
- ☁ Other: _____

5: What is your relation to the person you care for?

(Please tick one box only)

- ☁ Partner
- ☁ Parent
- ☁ Grandparent
- ☁ Sibling
- ☁ Other family. Please describe: _____
- ☁ Non-family. Please describe:_____

6: Do you and the person you care for live in the same household?

(Please tick one box only)

- ☐ Yes, live together → if yes: go to question X1
- ☐ No, live separately

→ if no: **Where does the one you care for live?**

(Please tick one box only)

☐	Lives with spouse
☐	Lives with other family
☐	Lives alone
☐	Nursing home
☐	Other: _____

7: Does the person you care for need any help in one of the following areas? If yes, is he/she partly or completely reliant on the help of others?

(Please cross one number for each line)

	Completely dependent	Partly dependent	No need for help
For health reasons: (e.g. medication intake, medical treatment, rehabilitation, therapy, etc.)			
For constitutional/ personal reasons: (e.g. washing oneself, dressing oneself, eating or going to the toilet)			
For mobility reasons: (e.g. at home or outside of the home, transport-related)			
For emotional/psychological/social reasons: (e.g. keeping company, giving the feeling of security, calming down)			
In the household: (e.g. homework, transport)			
For the organisation of finances: (e.g. helping to pay bills from the PATIENT's money)			
For financial reasons: (e.g. by financial support / paying bills for the patient from OWN money)			
Organisation of care: (e.g. taking up the contact to care providers)			

8: How long have you been providing care for the person you care for?

(Please enter the exact number of years and months. If you don't remember the exact number please try to estimate)

Years |__||__| Months ||__||__|

9: How many <u>hours per week</u> do you provide assistance, care, supervision or companionship to the person you care for?

(Please enter the exact number of hours per week. If you don't remember the exact number please try to estimate)

Hours per week |__||__|

10: Has your employment status changed <u>as a result</u> of your caregiving duties?

(Please tick one box only)

- ☐ No → if no: go to question **X7**
- ☐ Yes → if yes: **what has changed in your employment?**
  - ☐ Early retirement
  - ☐ Changed jobs
  - ☐ Began working
  - ☐ Family leave
  - ☐ Quit job
  - ☐ Leave of absence
  - ☐ Laid off
  - ☐ Increased hours
  - ☐ Decreased hours
  - ☐ Other: _____

11: Do you sometimes wish for more social support from friends and family in order to manage the caregiving tasks?

☐ No ☐ Yes

6.12 Annex 8 – Study information sheet (English sample draft)

Short version of study information – separate versions for patients and caregivers under construction

Effects and acceptance of SENACA® for the self-management of chronic diseases

Exploring effects and acceptance of an ICT-based self-management support system for patients with chronic conditions and informal caregivers on symptoms, clinical outcomes, behaviour change and quality of life: a pre-experimental study

What we want to inform you about:

We would like to invite you to participate in our research project. We want to find out, how people living with chronic diseases and their caregivers manage these conditions. You have a heart disease, diabetes, the chronical lung disease COPD and/or a hip- or knee-replacement. Therefore, we hand out this paper to you.

Your doctor will advise you on the further options for your treatment.

What we want to find out in our study:

Our aim is to test the effects and acceptance of an online system called SENACA®. This is an online health program for the self-monitoring of chronic diseases.

What participating in the study will mean to you:

As a participant (one patient and one caregiver) you will get an introduction session to the online SENACA® health program before using the program at home for the following 100 days.

In order to test the effect and acceptance of the health program you will fill a questionnaire on day 0, 50 and 100 after start and let blood samples, weight measures and Body Mass Index (BMI) be taken by your doctor. The research project will last for you for 100 days.

What benefits and risks are linked to your participation in the study:

You will have free access to the SENACA® health management program during a period of 12 months. As a participant you will not be exposed to any bodily risks or psychological stress.

What are your rights as a study participant:

You are free to decide whether you want to participate or not. If you decide not to participate, it will not influence your on-going medical care. You are free to withdraw from the study at any given time during the study period without giving reasons.

During the study period we collect medical information and blood samples from you. In the case you decide to withdraw, they will be destroyed after the end of the study.

What are your responsibilities as a study participant:

If you participate in the study, you are obliged to follow some rules for your own security. During an introduction session to the online SENACA® health program you will get all the necessary information about using the devices.

What happens to your data:

We fulfill all legal regulations of data protection. Your data will only be used in this specific study. All persons involved in the study are subject to a duty of confidentiality.

What you agree to by signing the consent sheet:

Apart from this short version you will find additional information on the following pages. These are an integral part of the study information. With your signature you give informed consent and accept the full document.

Who to contact for further information:

Your questions can be answered anytime.

Questions concerning the study:

Jörg Haslbeck, principle investigator

Careum Research

Pestalozzistrasse 3

8032 Zürich

+41 43 222 64 10

joerg.haslbeck@careum.ch

Technical questions and support:

EMN European Medical Network,

Seestrasse 42

CH-8802 Kilchberg ZH

Email: support@emn.net

Help-Desk: +41 44 387 40 85

Long version of study information

Effects and acceptance of SENACA® for the self-management of chronic diseases

Exploring effects and acceptance of an ICT-based self-management support system for patients with chronic conditions and informal caregivers on symptoms, clinical outcomes, behaviour change and quality of life: a pre-experimental study

Sponsor: European Union (EU), represented in Switzerland by the State department for Education, Research and Innovation SBFI.

Dear Madam, Sir

My name is Jörg Haslbeck and I am responsible for this research project.

1. Selection of people eligible to take part in this study

Any people with one or multiple of the following diseases can participate: heart disease (heart failure), diabetes, the chronical lung disease COPD and/or hip- or knee-replacement. You must be 50 years or older and receive support from a caregiver who is at least 18 years old. You should have sufficient skills for using the online SENACA® health program. There must be a written informed consent.

Participation is not possible for people who currently suffer from an acute disease or who went through a recent surgery (except a hip or knee surgery for those living with a hip- or knee-replacement). If you currently suffer from a mild or severe psychological disturbance you cannot take part in the project. Participation is neither possible if you have problems to read or write, or if you are not able to sufficiently speak the local language. If you are currently taking part in another study, you cannot participate. Participation is neither possible in case of a missing informed consent.

2. Goals of the study

This study wants to test if and how the online SENACA® health program supports the process of dealing with a chronic disease. The health program is designed to improve one's own health management. To this end, you will actively work on the topics of nutrition, exercise, and social exchange.

3. General information about the study:

Information and communication technologies (ICT) that utilize the Internet or mobile technologies can address the challenges in the life with chronic diseases. They can support a self-reliant way of dealing with the disease. The online SENACA® health program consists, on the one hand, of a secured website with modules about the topics food and physical activity, a personal logbook, statistics, health records and a knowledge base about chronic diseases. On the other hand, it entails devices for self-monitoring the disease at home (f.ex. blood pressure, weight, physical activity).

The aim of the international USECARE AAL study project is to improve the online SENACA® health program and to test its usability. The study will be conducted in Switzerland, Norway and Israel. In Switzerland there will be each 12 patients plus their informal caregiver participating, being 96 participants in total in the three participating countries.

The plan of the study is that the participants will be trained in the online SENACA® health program before using the devices and programs during 100 days at home. During that time,

they will have three consultations with their doctor in order to collect blood samples for monitoring their bodily functions. On day 0, 50 and 100 they will fill questionnaires about the online SENACA® health program.

The study is carried out according to the laws in Switzerland. Apart of that we follow the internationally recognized directives. The study was examined and approved by the respective cantonal ethics committee.

You can find a description of the study on the website www.senaca.ch, run by the developers of the online SENACA® health program.

4. Procedure for the participants

- The study duration for participants is 100 days. Added to this will be half a day for training in the online SENACA® health program before the start of the study. After the 100 days you will probably be invited to an interview or group discussion.
- The study results will be available starting from 2017.
- You will be invited to 3 appointments with your doctor for taking blood samples.
- Place, amount and duration of measurements and visits:

Automated measurements by the online SENACA® health program:

- blood pressure, heart rate (OMRON 708-BT)
- Weight, body fat (OMRON BF206-BT)
- physical activity (Striiv fusion)
- according to your disease:

heart disease: Sp02, heart rate (NONIN Onyx II BT 9560)

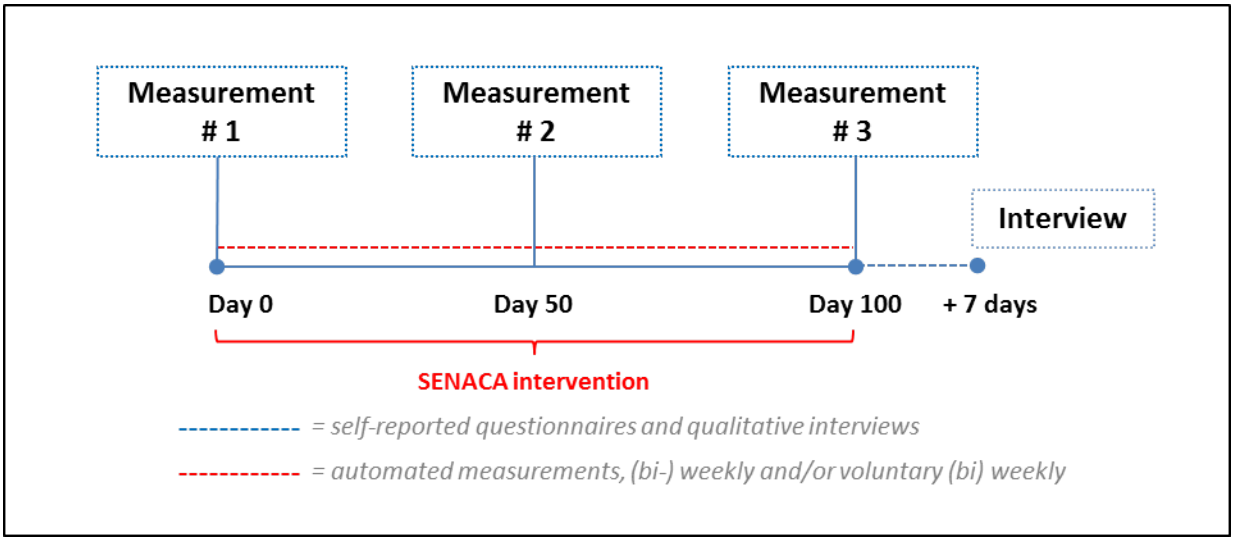
diabetes: fasting glucose (AccuCheck Connect or Fora G31 B)

lung disease: spirometry (Vitalograph Asma-1 or Spirotel Mobile Mini-Lab)

3 blood samples (day 0, 50, 100) with 1-2 tubes to measure cholesterol (LDL and HDL), triglyceride and HbA1c.

3 times (day 0, 50, 100) interrogation with a questionnaire to usability, quality of life, health behaviour, utilization of health services.

1 telephone interview (after the end of the study) about your experiences with the online SENACA® health program.



- These examinations are required in order to assess how the measurement and wellbeing evolve while using the online SENACA® health program.

5. Rights of the participants

You only take part in this study if *you* want. No one is allowed to persuade you or to push you into the study. Your current medical treatment will be exactly the same, also if you do not join. You do not have to explain why you do not want to join the study. Also if you decide to participate, you are entitled to change you decision anytime. You do not have to explain, why you no longer want to take part in the study. Afterwards, you can tell us about your experiences with the online SENACA® health program in a telephone interview.

You are allowed to ask questions anytime during the study. Please forward your questions to the appropriate person listed at the end of this study.

6. Participant responsibilities

In case of participation you have to follow certain rules. This is necessary for your own safety and health. We will support you at our best. As a study participant you are required to follow the technical advice of the doctor in charge of the study and to the stick to the study plan.

7. Benefits for the participants

The online SENACA® health program is available to the participants for 12 months free of charge. Joining this study can bring you some changes in the attitudes towards health promoting behaviour. You may then possibly bring about changes in the way you deal with your health. In addition, the results of this study may be important for others with the same condition.

If you participate over the whole period of the study, you can keep the measuring devices which you will receive at the beginning of the study. Additionally, you will be entitled to have free access to the online SENACA® health program for further six months in order to use the online services.

8. Risks and burdens for the participants

The participants are not exposed to bodily risks or psychological stress. Inconveniences may occur in connection with the examination of your blood because 10 - 20 ml (approximately 2 to 3 tablespoons) of blood gets taken with a syringe.

Participating in this study is free of charge for you.

9. Data safety

For this study we will use your personal and medical data. This data will be coded. This means, that all data which could identify you (by name, date of birth etc.) are replaced by a specific code, so that your data are not accessible to people who do not know the code.

Within the Institute of Nursing Sciences at the University of Basel, the data without encryption may be viewed by authorized and clearly designated persons. The key remains in the institution.

It may be that the study will be reviewed during its course. This can be done by the authorities, which checked and approved the study previously. This can also be done by the institution which is financing the study. They all make sure that the rules are respected, and your safety is not compromised. This may entail that, the leader of the study may have to open any of your personal and medical data for official check reasons. It may also be that, in the event of damage, the representative of the insurance has to look at your data. This must be limited to the data which are necessary to use in order to handle the case of damage.

All people involved in any form into this study are subject to a duty of strict confidentiality. We are not going to publish you name in any publication nor report, whether print nor online.

To guarantee data security, a high security server will be used. Data collected by the home-monitoring devices will be encrypted by a device at your home. The researchers in the study can access the your personal health data using the agreed-upon login information (user name and password).

The sponsor in Switzerland is responsible for compliance with national and international guidelines for data resp. the representative of the foreign sponsor in Switzerland (State Secretariat for Education, Research and Innovation SERI).

10. Further use of the material and data

You can exit the study anytime if you want. We will anyway make use of the medical data and of the biological material (blood samples) we collected from you. Otherwise the study would lose its sense.

After that we will anonymize your data and your material, and we will permanently delete your name on it. No one will then be able to know that the data and the material belonged to you.

11. Compensation for participants

You will receive no compensation for participating in this study. However, the online SENACA® health program is available to you free of charge during 12 months.

12. Insurance coverage

Eventual damages which will be caused by the online SENACA® health program resp. by your immediate participation in the study, will be covered by the sponsor's business liability insurance of the University of Basel. Category A studies do not require a specific insurance certificate.

13. Financing of the study

The study is mainly financed by the European Union (EU) (representative in Switzerland: State Secretariat for Education, Research and Innovation SERI). The remaining part is covered by participating members of the USECARE AAL consortium, f.ex. Careum Foundation, Zurich, or EMN European Medical Network AG, Kilchberg.

14. Contact persons

In case of any ambiguities, fears or emergencies that occur during the study or after, you can always contact one of these persons.

Director of the study
Jörg Haslbeck, principal investigator
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6.13 Annex 9 – Informed consent (English sample draft)

Sheet of consent

Written consent about the participation in the study

- Please read this form carefully
- Do not hesitate to ask if you don`t understand or if you want to know something

Study number: [pending, via CEC ZH]	
Title of the study:	Effects and acceptance of SENACA® for the self-management of chronic diseases Exploring effects and acceptance of an ICT-based self-management support system for patients with chronic conditions and informal caregivers on symptoms, clinical outcomes, behaviour change and quality of life: a pre-experimental study
Responsible institution or sponsor:	Institute of Nursing Science INS, University of Basel, Bernoullistrasse 28, CH-4056 Basel
Place of implementation:	Zurich
Director of the study: First name und surname in capital letters:	Dr. Jörg Haslbeck
Study participant First name und surname in capital letters: Date of birth:	☐ female ☐ male

- I received oral and written information about the purpose and course of the study with the online SENACA® health program, about the expected effects, about possible benefits and disadvantages as well as about eventual risks.
- My questions related to the participation in this study have been answered to my satisfaction. I can keep the written study information from [date / version] (two pieces) and get a copy of my written consent. I accept the contents of the above-mentioned study and its study information.
- I take part in this study voluntarily. I may withdraw my consent to participate at any time without giving any reason, and without any changes in the further medical care.
- I had enough time to make my decision.
- I know that my personal details and body material can be further used for research purposes only in a coded form. I agree that only the appropriate experts of the sponsor of the study, of the the authorities and the cantonal ethics committee can have access to my original data for testing and verification purposes, however under a strict confidentiality.
- I am aware of the need of fulfillment of the participant criteria mentioned in the study information during the study. For the sake of my health I may be excluded from the study by the study director at any time.

Place, date	Signature study participant

Confirmation of the study doctor: I hereby confirm that I have explained the participant the nature, significance and implications of the study. I declare to fulfill all obligations related to this study and in accordance with applicable law. Should I learn at any time during the course of the study, of aspects that could affect the willingness of the participant to participate in the study, I will inform him/her immediately about it.

Place, date	Signature study doctor

6.14 Annex 10 – Interview guides (English sample draft)

Interview guide for patients finishing the intervention period

		First priority questions	Area to cover
Opening question	1	Please describe your overall experienced with SENACA?	Overall experience
Initial experience	2	Please describe your use of computers, mobile devices or other modern electronics in relation to health before the intervention	Prior ICT experience
	3	Describe your thoughts about SENACA when you first heard about it	Technology readiness
	4	Please elaborate on the introduction session given in advance	SENACA improvements
Experiences	5	Please describe some factors that made it easier for you to use the program	Facilitators/barriers
	6	Please elaborate on positive experiences produced by using SENACA	Facilitators/barriers
The specific use	7	Please describe your use of the different elements in SENACA - which one did you find most useful?	SENACA improvements, eHealth literacy
	8	Please describe the assistance you got from other people e.g. family in order to use SENACA	Age barriers
	9	Please elaborate on your health behaviour in terms of physical activity, alcohol consumption etc. during the SENACA period	Behaviour change
	10	Please elaborate on your level of involvement in managing your health during the SENACA period	Self-management
Future	11	From your perspective what modules, elements etc. should be changed in SENACA in order to improve it?	SENACA improvements
		Second priority questions	
		How did you experience the technical support in situations of technical problems?	SENACA improvements
		Pleace describe your thougths about having your healt data on a computer software	Data security
		Describe how SENACA did influence your feeling of indendence of other people, family members etc.	Autonomy
		Please elaborate on your experiences related to the interaction with other people using SENACA (the forum)	Self-management
		Please describe your use of healthcare services during the study period	Healt care utilization
		Please describe your expectation of using electronic or online tools in relation to your illness in the future	Usability and older adults

Interview guide for the drop-outs

		First priority questions	Area to cover
Opening question	1	Please describe your overall experience with SENACA?	Overall experience
Initial experience	2	Please describe your use of computers, mobile devices or other modern electronics in relation to health before using SENACA	Prior ICT experience
	3	Describe your thoughts about SENACA when you first heard about it	Technology readiness
	4	Please elaborate on the introduction session giving in advance	SENACA improvements
Reasons for withdrawing	5	Please describe the reason(s) why you withdraw from using SENACA?	Facilitators/barriers
	6	Please elaborate on positive (or negative) experiences produced by using SENACA	Facilitators/barriers
	7	Please describe barriers for you using the program	Facilitators/barriers
Future	8	From your perspective what should be changed in SENACA in order for you to use SENACA?	SENACA improvements
		Second priority questions	
		How did you experience the technical support in situations of technical problems?	SENACA improvements
		Pleace describe your thougths about having your healt data on a computer software	Data security
		Please elaborate on your health behaviour in terms of physical activity, alcohol consumption etc. during the SENACA period	Behaviour change
		Please elaborate on your level of involvement in managing your health during the SENACA period	Self-management
		Please describe your use of the different elements in SENACA - which one did you find most useful?	SENACA improvements, eHealth literacy
		Please elaborate on your experiences related to the interaction with other people using SENACA (the forum)	Self-management

6.15 Annex 11 – Interview guide – usability tests

1) What do you think about the usability of the system, the different modules and the devices?
    a. Triggers: user-friendliness, navigation, steps to accomplish a task
2) What do you think about the graphical presentation of the results?
3) Is the meaning of the used colors throughout the website clear and easy to understand?
4) Have you encountered any problems while using the system? If yes, what kind problems?

6.16 Annex 12 – Questionnaire

The following questions are used to evaluate how difficult / easy different areas and tasks of the website were understood.

How easy was it to setup the SENACA system?

Difficult	0	1	2	3	4	5	Easy

Comments/problems:

_____

Learning to use the system

Difficult	0	1	2	3	4	5	Easy

Comments/problems:

_____

_

Navigate within the system

Difficult	0	1	2	3	4	5	Easy

Comments/problems:

_____

_

Readability of content

Difficult	0	1	2	3	4	5	Easy

Comments/problems:

_____

_

It requires the fewest steps possible to accomplish what I want to do with it.

Disagree	0	1	2	3	4	5	Agree

Comments/problems:

_____

___

Error messages

Unhelpful	0	1	2	3	4	5	Helpful

Comments/problems:

_____

_

Graphical presentation of the monitoring data (weight, blood pressure etc.)

Confusing	0	1	2	3	4	5	Very clear

Comments/problems:

_____

_

It is easy to use the module: Monitoring

Disagree	0	1	2	3	4	5	Agree

Comments/problems:

_____

_

It is easy to use the activity tracker.

Disagree	0	1	2	3	4	5	Agree

Comments/problems:

_____

_

It is easy to use the module: Nutrition

Disagree	0	1	2	3	4	5	Agree

Comments/problems:

_____

_

It is easy to use the module: Activity

Disagree	0	1	2	3	4	5	Agree

Comments/problems:

_____

_

It is easy to use the module: Health literacy

Disagree	0	1	2	3	4	5	Agree

Comments/problems:

_____

_

It is easy to use the blood pressure device.

Disagree	0	1	2	3	4	5	Agree

Comments/problems:

_____

_

It is easy to use the scale.

Disagree	0	1	2	3	4	5	Agree

Comments/problems:

_____

_

It is easy to use the activity tracker.

Disagree	0	1	2	3	4	5	Agree

Comments/problems:

_____

_

6.17 Annex 13 – Qualcomm 2net Security Q&A

What is the typical data flow for medical data?

Medical data generated by the medical devices are captured by the Hubs in the homes of the patients, encrypted and transmitted through the cellular networks on the 2net service platform, which for Europe is operated and maintained by Qualcomm IT resources in Amsterdam in the Netherlands. Then the data are collected by the customers and the data are then erased on our Service Platform once we are sure that the customers have correctly collected the medical data.

Is there any encryption between measurement device and 2net hub? Bluetooth mode 1,2,3?

BT 4.0 (BLE) native security supported. End-to-end data encryption from 2net Hub to 2net Service Platform: AES-128 bit encryption.

When is medical data deleted from secure storage after it has been successfully transferred?

Data is deleted automatically after a few days (typically 72-96 hours). Data is maintained temporarily to allow Qualcomm Life (QCL) perform issue troubleshooting and root cause analysis.

Who is the owner of QCL's data centre in Amsterdam?

The data centre in Amsterdam is co-location and operated by our partner Equinix.

Could the US Patriot Act force QCL to give access to patient data under certain circumstances?

Data hosted in EU by QCL is very unlikely to be subject to the U.S. Patriot Act.

1. To date, Qualcomm Life, Inc. has never received a request for information pursuant to the USA Patriot Act.
2. Qualcomm Life believes it is at very low risk of ever receiving a request from a US official pursuant to the Patriot Act given the nature of the data we process, which is:
   (a) binary data that cannot be read without decoding keys held by the medical device manufacturers,
   (b) which binary data is tied solely to medical devices and not specific individuals, even if decoded, and
   (c) such binary medical device information is highly unlikely to impact a matter of "foreign intelligence" or "international terrorism" as required for a request under Section 215 of the Patriot Act.
3. The 2net data hosted by Qualcomm Life, although not "anonymized" under some countries laws, does not contain information from which – without more information from the EU-based client – the government would be able to identify any individuals. The only identifiers are device and hub serial numbers. Qualcomm Life does not keep the names associated to the device and hub serial numbers, although the customer may. Without the association, which would have to be provided by an EU customer, the US government would be unable to match any readings to an individual.
4. In the highly unlikely event a request was made of Qualcomm Life under the Patriot Act for the 2Net data, Qualcomm Life anticipates it would take the necessary steps to oppose such a request given our position in (2)(c) and 3 above.

Does every client have its own physically separated secure storage or is it just logically separated?

No, data is logically separated, i.e. co-mingled.

Which people have access to secure storage (admin, technicians, support staff,...) and do they have to sign an NDA?

Only EU QCL employees and approved subcontractors under NDA have access to the data. Physical access to the location is also limited to our partner Equinix and Qualcomm employees.

Which safety objectives exist and how are they ensured (data confidentiality, integrity, availability...?)

Encryption in transit and at rest (TDE). 24/7 system and application monitoring/alerting.

Are log files created? Do they contain patient details (device id, hub id,...)? Are they deleted automatically?

Log files are created and these may contain de-personalized hub/device details. No personal patient details are stored. Certain log files are required to be maintained for eDiscovery/forensics for up to 7 years.

How about 2net hub's remote maintenance? Who is allowed to do this?

Only QCL Employees are allowed access the hubs remotely. Remote maintenance activities include upgrades to Hub Software and device specific modules and also retrieval of diagnostic logs.

6.18 Annex 14 – Threat table

A total of 29 possible threats and unwanted incidents were identified in the risk assessment. In this table, the threats are uniquely identified by a combination of letters and numbers. The letters indicate which of the information security aspects confidentiality (c), integrity (i), or availability (a) the threat is related to, with the numbers giving a consecutive numbering within each category.

ID	Threat / Unwanted incident	Cause	Likelihood	Consequence	Risk	Comments (e.g. existing and proposed measures)
Confidentiality threats						
c1	Unauthorised access to sensitive information stored in the (cloud?) servers, i.e. access to both person identification data ("DB Users") and to health information ("DB Data") Qualcomm: no person identification, monitor data stored temporarily, for a short time SENACA: both servers must be exposed	Unencrypted data can be seen by administrators and operators at the operating environment.	**High**	**Small** Administrators and operators do not know the patients, who may be in another country.	**Low**	Are stored data encrypted? Data processor agreement? Logging of access? Log inspection and alarms? Professional secrecy and employment contract?
c2		Servers are attacked by casual external persons (hackers)	**Low??** Depends on security measures at operating centre, assume Qualcomm is professional	**Small** for patients: Hackers do not know the patients. (**Severe** for the reputation of the system/service, see threat c3 below)	**Low (Medium)**	Two types of "hackers": 1. "Scriptkiddies" who want to prove what they are able to 2. Persons who want to obtain money (sell data, or use it for blackmailing)
c3		Servers are deliberately attacked by external persons who wants to see particular data	(very) **Low** What should the motivation be?	**Severe** … mainly for the reputation of the service	**Medium**	
c4	Unauthorised access to sensitive information transferred via Internet from Qualcomm Backend to SENACA servers	Network attack, wiretapping, man-in-the-middle	**Low** Encrypted transfer (SSL/TLS).	**Moderate** … for the reputation of the system/service, but no person info	**Low**	It is possible, but not so easy. (SSL weaknesses…)

ID	Threat / Unwanted incident	Cause	Likelihood	Consequence	Risk	Comments (e.g. existing and proposed measures)
c5	Unauthorised access to sensitive information transferred via mobile network from Qualcomm Hub in patient's home to Qualcomm Backend	Network attack, wiretapping, man-in-the-middle	**Low** Encrypted, AES-128	**Moderate** … for the reputation of the system/service, but no person info	**Low**	
c6	Unauthorised persons can login to the user's account (web site) and read sensitive information.	Guess or find username and password	**Moderate**	**Moderate** Info for one user only	**Medium**	Password only is too simple authentication mechanism. Requirements for password strength? Information, awareness raising Avoid storing/remembering password in the web client.
c7	Unauthorised access to monitoring data transferred via Bluetooth at home	Wiretapping Wrong pairing	**Low** Devices have to be "paired" one-to-one	**Small** It is within the house/home, only values, not much info	**Low**	It is always at home, where the HUB is.
c8	Unauthorised persons can access the user's account (web site) via the mobile phone (app?) and read sensitive information	Too weak authentication mechanism in the mobile phone solution (??)	**??** (Too little info about this solution)	**Moderate**	**??**	Which authentication mechanism(s) for login to the app? (Is it an app?) In addition, information/awareness to users to use PIN for entering the mobile phone.
Integrity threats						
i1	Data/information stored in the (cloud?) servers is modified. - In Qualcomm Backend - In SENACA servers	Accidentally modified by administrators or operators at the operating environment.	**Low** Assume professional organisations with security measures	**Small** for the patient, data and information will be checked.	**Low (Medium)**	Are stored data encrypted? Data processor agreement? Logging of access? Log inspection and alarms?

ID	Threat / Unwanted incident	Cause	Likelihood	Consequence	Risk	Comments (e.g. existing and proposed measures)
i2		Deliberately modified by administrators or operators at the operating environment.	(Very) **Low** What should the motivation be?	**Severe** for the reputation of the service/system.	**Low (Medium)**	Professional secrecy and employment contracts. Educate the users to control/check their own data after registration
i3		Accidentally modified by external persons (hackers) or by malware	**Low**		**Low (Medium)**	Two types of "hackers": 1. "Scriptkiddies" who want to prove what they are able to 2. Persons who want to obtain money (sell data, or use it for blackmailing)
i4		Deliberately modified by external persons	(Very) **Low** What should the motivation be?		**Low (Medium)**	
i5	Modification of monitoring data transferred via Internet from Qualcomm Backend to SENACA servers	Network attack, malware, man-in-the-middle	**Low** Encrypted transfer (SSL/TLS).	**Small** for the patient, data and information will be checked. **Severe** for the reputation of the service/system.	**Low (Medium)**	It is possible, but not so easy. (SSL weaknesses. Authorities like NSA…)
i6	Modification of monitoring data transferred via mobile network from Qualcomm Hub in patient's home to Qualcomm Backend	Network attack, malware, man-in-the-middle	**Low**		**Low (Medium)**	
i7	Data from the web site is modified in the transfer to servers – and the modification is not detected	SW errors	**Low** Tested during SW development.	**Small** for the patient: data and information will be	**Low (Medium)**	Testing during system development. Educate the users to control/check their own data after registration

ID	Threat / Unwanted incident	Cause	Likelihood	Consequence	Risk	Comments (e.g. existing and proposed measures)
i8	Unauthorised persons can login to the user's account (web site) and modify data/information.	Guess or find username and password	(Very) **Low** What should the motivation be?	checked. (It could be Severe if data was to be used for change of treatment or medication.) **Severe** for the reputation of the service/system.	**Low (Medium)**	Password only is too simple authentication mechanism. Requirements for password strength? Information, awareness raising Avoid storing/remembering password in the web client.
i9	Legitimate users modify data/information on their own web site	Accidentally, by mistake (e.g. because poor user interface?)	**??** To be experienced.		**??**	(Who will register laboratory test results?)
i10	Modification of monitoring data during transfer via Bluetooth at home	SW/HW errors?	**Low?** Not possible?		**Low (Medium)**	
i11	Registration of fake/false measurements	Unauthorized persons, e.g. children, "play" with the monitoring equipment so that fake/false values are registered for the user	**Moderate**	**Small** for the patient: data and information will be checked. (It could be Severe if data was to be used for change of treatment or medication.)	**Low**	Information to the users – that all measurements will be transferred (always on?). Educate the users to control/check their own data after registration. Is it possible for the user to delete their own registrations? – Then it could be a risk that too much is deleted. Is it possible for the user to insert comments to their own registrations?
i12	Modification of data/information from mobile phone (app?)	Deliberately, by unauthorised persons, by getting hold of authentication information	(Very) **Low?** What should the motivation be?	**Small** for the patient, data and information will be checked. **Severe** for the	**Low (Medium)**	Which authentication mechanism(s)? Login to the app? (Is it an app?) In addition, information/awareness to users to use PIN for entering the mobile phone.

ID	Threat / Unwanted incident	Cause	Likelihood	Consequence	Risk	Comments (e.g. existing and proposed measures)
i13		Accidentally, by mistake (e.g. poor user interface?)	**??** To be experienced	reputation of the service/system.	**??**	
i14		SW errors	**??**		**??**	
Availability threats						
a1	Users cannot log in to their web site	Servers are down (different reasons) Disk crash Data are damaged	**Low** (Assume backup and quick fix…) Virtualisation, redundancy	**Moderate** - for the patient, users may be demotivated. **Severe** for the reputation of the service/system.	**Low (Medium)**	Any notification to users from project or service provider?
a2		Network problem (locally at patient's side, mobile network or Internet connection)	**Low?**		**Low (Medium)**	Network conditions at the patient's side (Internet and mobile network) must be among the inclusion criteria.
a3		Problem with user's own device (PC, pad, mobile phone)	**Moderate**	**Moderate** Users may be demotivated if no help	**Medium**	Private problem. Any support from the project or service provider? Education/training at start of project.
a4	Monitoring data are not being transferred to the servers	Servers are down (different reasons)	**Low**	**Small** for the patient. **Severe** for the reputation of the service/system, and motivation for use. (Depends how long the problem lasts.)	**Low (Medium)**	Any notification from project or service provider?
a5		Network problem (locally/bluetooth, mobile network or Internet connection)	**Low?**		**Low (Medium)**	Bluetooth: Too long distance? Visual. Requires some education and training at the start of the project
a6		Technical problem with the local access point (aggregator/hub) in the user's home.	**Low?** Assume this is a stable and well tested technology		**Low (Medium)**	Any support from the project or service provider? User check? Error message? Can Qualcomm remotely check if hub is alive?

ID	Threat / Unwanted incident	Cause	Likelihood	Consequence	Risk	Comments (e.g. existing and proposed measures)
a7		Problem with the monitoring unit(s)	**Low** Assume this is a stable technology.		**Low (Medium)**	Any support from the project or service provider? Spare parts, backup equipment.