D8.1 Evaluation framework for SmartCare Draft version

Based on the SPIRIT guideline (WP8)

Version 1.0, 3rd October 2013

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Document information

Abstract

Contains the scientific protocols for the SmartCare trials.

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Outstanding Issues

Section 3.2.1 Item 11a: Pathways will be inserted here in a later release.
Examples of Consent forms to be added to Appendix.

Filename

D8.1 v1.0 Evaluation framework for SmartCare

Statement of originality

This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.

Executive summary

This deliverable (D8.1) is the scientific protocol for the SmartCare project. The protocol presents descriptions of all relevant information for carrying out an evaluation of ICT supported integrated care.

The protocol is based on the SPIRIT guideline for scientific protocols adapted to cohort studies. It presents the background of the evaluation, objectives, methodologies used for selection of participants, data collection, data management, statistics, monitoring and ethics. The protocol describes the evaluations of pilot sites along with the overall evaluation of SmartCare.

Table of Contents

1. Introduction

1.1 Purpose of this document

In SmartCare, WP8 requires a scientific protocol as a deliverable. This document describes the protocol for the individual pilot sites and in brief for the overall SmartCare project as well.

This document is produced based on the SPIRIT guidelines for scientific protocols (Chan et al. 2013) modified to fit a cohort study design, so only relevant items for cohort studies are considered and presented in this document.

This evaluation framework constituting D8.1 is structured as and intended to become a scientific protocol. Thus, throughout the text, when referring to the current document, it is described as a protocol as opposed to an evaluation framework.

The document will be reissued as further details are agreed.

1.2 Structure of document

Most of the headings in the document below include an Item number. These item numbers correspond to the way headings are presented in the SPIRIT guideline.

Section 2 provides background information on the trial, including the trial objectives and trial design

Section 3 describes the participants, interventions and outcomes, including inclusion and exclusion criteria.

Section 4 sets out data collection methods, while sections 5 and 6 cover data management and statistical methods respectively.

Finally, section 7 covers methods monitoring, section 8 ethics and dissemination, and section 9 contains references.

1.3 Glossary

Meta-analysis	Statistical analysis pooling the results of different studies by pooling odds ratios or relative risks.
Stopping rules	Stopping rules should be perceived to belong to the pilot or project level. So, rules for stopping include any indicator used as flag-raising to indicate safety problems related to the interventions.

2. Background information on trial

2.1 Item 6: Background and rationale

2.1.1 Item 6a: Description of research question and justification for the trial

Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention

The trial will evaluate the functions and impacts of the SmartCare pilot services from the point of view of the different principal roles/stakeholders, such as end users (care recipients), voluntary and non-voluntary informal carers, formal care staff/professionals, managers and fund-holders. Evaluation of integrated care service delivery processes (process evaluation) will improve the current scientifically based knowledge base on barriers and facilitators towards integrated care delivery. Beyond this, scientific knowledge will be generated on outcomes of integrated care service delivery from the perspective of all actors involved. Apart from generating a number of self-standing deliverables, this workpackge will directly feed into WP9 with a view to support further exploitation of project outcomes beyond the project duration by relevant stakeholders and wider dissemination within the project duration.

2.1.2 Item 6b: Explanation for choice of comparators

Comparators were chosen to be current delivery of health and social care processes, as provided by pilot sites individually. The current health and social care services will be described for the evaluation of SmartCare. The project uses local scenarios as the comparator in order to enable the evidence generated to contribute to local decision making on using the technologies. It was neither possible nor desirable to standardise the usual care in all pilot sites before carrying out the research project. Comparators were running simultaneously to the intervention, in most pilot sites divided by geographical aspects. Thus, the control groups were as similar as possible to the intervention groups. In addition, a number of possible confounding factors were measured for all participants.

2.2 Item 7: Specific objectives or hypotheses

The overall aim of the scientific studies carried out in SmartCare is: To identify the differences induced by implementing ICT supported integrated health and social care.

Any impact that ICT supported integrated health and social care might have on all users will be the subject of analyses according to the framework presented in the MAST model (Kidholm et al. 2012).

In addition, the objectives that will be tested in SmartCare are:

- Difference in number of contacts to health care.
- Difference in number of contacts to social care.
- Differences in use of health care services.
- Differences in use of social care services.
- Differences in costs.

- Differences in organisational aspects caused by implementing ICT supported integrated care.
- Difference in end-user empowerment.
- Difference in end-user satisfaction.

The specific data that will be collected in order to answer the objectives are specified in Item 12 on outcomes (see section 3.3 below).

2.3 Item 8: Description of trial design including type of trial, allocation ratio, and framework

It is important to note, that the overall study design in SmartCare is divided into three phases:

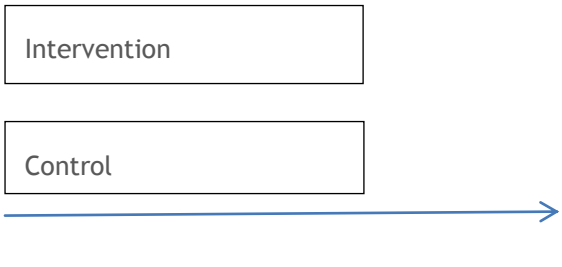
1) First wave pilot sites (cohort)
2) Second wave pilot sites (cohort)
3) Overall SmartCare study (meta-analysis)

This division into phases means that the pilot sites are required to adhere to one study design (controlled cohort studies), which will afterwards be pooled in a meta-analysis.

Data will be collected prospectively and with an allocation ratio of 1:1.

3. Methods; Participants, interventions, outcomes

The set-up of all SmartCare pilot sites is cohort studies, i.e. a group of people with similar characteristics are followed over a period of time. The groups are split into halves, so half of the population receives the intervention, and the other half receives usual care. The two groups run in parallel. The rules of division into groups are allowed to differ between pilot sites; so in some pilots there will be randomisation, whereas in others, geographical aspects decide the groups. Sufficient calculations on possible confounding from geographical division will be carried out. In addition, the overall meta-analysis with subgroups based on sampling will provide knowledge on the measured differences in effect sizes that can be explained by study design.



Measurements on primary and secondary outcomes within all MAST domains will be carried out for both groups allowing for comparisons of all outcomes.

3.1 Item 9: Description of study settings and list of countries where data will be collected

Study settings include ten pilot sites and all relevant types of services offered to people enrolled. Services include health and social care provided by public or private institutions, volunteer sector or informal carers.

Regions included in SmartCare as pilot sites are:

- 1st wave:
  - Scotland, UK
  - Region of Southern Denmark, DK
  - Aragon, ES
  - FVG-ASS1, IT
- 2nd wave:
  - Kraljevo, SRB
  - Tallinn, EST
  - South Karelia, FIN
  - Uppsala, SE
  - Attica, GRE
  - North Brabant, NL

Study settings include all settings that are in any way relevant for the provision of care, i.e. hospitals, GP's offices, users' homes and volunteer service providers' offices.

3.2 Item 10: Inclusion and exclusion criteria for participants

Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions.

Inclusion criteria for end users: provided with both health and social care.

- Falls prevention.
- Congestive heart failure: RSD.
- Frail elderly: Aragon, Italy.

Interventions will be provided by a combination of health care, social care, volunteer sector care providers, and informal carers. Thus, the professionals that are involved in providing any type of health and/or social care for the included citizens will be enrolled as intervention performers and as users of the interventions.

Population samples will be drawn either by randomisation or consecutive inclusion of either intervention or control end-users determined by geographical areas.

3.2.1 Item 11a: Interventions for each group

Interventions for each group with sufficient detail to allow replication, including how and when they will be administered.

Pathways are currently being finalised, and will be inserted here in a later release.

3.2.2 Item 11b: Criteria for discontinuing or modifying allocated interventions for a given trial participant

Intervention might be modified according to:

1) End users' wishes of data sharing across involved sectors.
2) End users' possibility to access data through the use of ICT.
3) Other users' possibility to access data through the use of ICT.

There is no strategy for discontinuing allocated interventions, since any additional treatment or admission to hospital is allowed in the study design.

3.2.3 Item 11d: Relevant concomitant care and interventions that are permitted or prohibited during the trial.

None

3.3 Item 12: Primary, secondary, and other outcomes

Primary, secondary, and other outcomes, including the specific measurement variables, analysis metric, method of aggregation, and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended.

All outcomes are presented in Table 1: Outcomes, metrics, timing and explanation for variables below, along with identification of variable, analysis metric, time point and explanation for inclusion of each variable. Also, the table indicates whether each variable can be included on a voluntary basis by pilot sites, or if they are required to collect data.

The mandatory variables are defined by the study aim and objectives, and will be used in the final analyses of the study.

The methods of aggregation depend on the scaling of the variable (numeric, categoric, binary) and the distribution (normally or not normally distributed).

Table 1: Outcomes, metrics, timing and explanation for variables

Measurement	Respondent / target group	Level of data	Level of detail	Mandatory/ voluntary	Preferred collection method	Timing of measurement	Reason
1. Overall service effectiveness and specific outcome measures							
Number of contacts, healthcare services	Citizen / client / carer	Individual level	Number	M	Registries	Baseline / mid-term / exit	Total number of contacts is 1) easy to establish (was there a contact or not), and 2) it is available in all sites.
Unplanned contacts, healthcare services	Citizen / client / carer	Individual level	Number	V	Registries	Baseline / mid-term / exit	Unplanned contacts is chosen because it is 1) easy to establish (was there an unplanned contact or not), and 2) it reflects both the aim of the interventions in clinical terms but also safety issues, organisational and economic aspects. At each site, the exact meaning and operationalisation of this outcome measure needs to be defined.
Number of contacts, social care services	Citizen / client / carer	Individual level	Number	M	Registries	Baseline / mid-term / exit	Total number of contacts is 1) easy to establish (was there a contact or not), and 2) it is available in all sites
Unplanned contacts, social care services	Citizen / client / carer	Individual level	Number	V	Registries	Baseline / mid-term / exit	Unplanned contacts is chosen because it is 1) easy to establish (was there an unplanned contact or not), and 2) it reflects both the aim of the interventions in clinical terms but also safety issues, organisational and economic aspects. At each site, the exact meaning and operationalisation of this outcome measure needs to be defined.
Number of contacts, volunteer sector services	Citizen / client / carer	Individual level	Number	M, if relevant in setting	Registries	Baseline / mid-term / exit	Total number of contacts is 1) easy to establish (was there a contact or not), and 2) it is available in all sites
Unplanned contacts, volunteer sector services	Citizen / client / carer	Individual level	Number	V	Registries	Baseline / mid-term / exit	Unplanned contacts is chosen because it is 1) easy to establish (was there an unplanned contact or not), and 2) it reflects both the aim of the interventions in clinical terms but also safety issues, organisational and economic aspects. At each site, the exact meaning and operationalisation of this outcome measure needs to be defined.
1.a Disease specific health status measures							
Blood pressure	Citizen / client	Individual level	Number	V	Registries	Baseline / mid-term / exit	Indicator for health status
Blood glucose	Citizen / client	Individual level	Number	V	Registries	Baseline / mid-term / exit	Indicator for health status (diabetics only)

Measurement	Respondent / target group	Level of data	Level of detail	Mandatory/ voluntary	Preferred collection method	Timing of measurement	Reason
Cholesterol	Citizen / client	Individual level	Number	V	Registries	Baseline / mid-term / exit	Indicator for health status
Anxiety	Citizen / client	Individual level	Scale	V	Questionnaire or interview	Baseline / mid-term / exit	Indicator for health status
Status/severity of primary condition	Citizen / client	Individual level	Scale or number	V	Registries	Baseline / mid-term / exit	Predictor of health outcome
1.b Generic health related / functional quality of life							
SF 36 v2	Citizen / client	Individual level	Scale	V	Questionnaire or interview	Baseline / exit	Might be affected by the intervention
Barthel	Citizen / client	Individual level	Scale	V	Clinical measurement	Baseline / exit	Indicator for health status
Timed up & go	Citizen / client	Individual level	Number	V	Clinical measurement	Baseline / exit	Indicator for health status
CASP-19 family carer QoL	Carers	Individual level	Scale	V	Questionnaire or interview	Baseline / exit	CASP-19 is used to specifically measure QoL of family carers. The measure has four domains: control, autonomy, pleasure and self-realisation. The scale contains 19 items. The domains have Cronbach's αs between 0.60 and 0.80. Correlations between the four domains range from 0.40 to 0.70. Concurrent validity has been assessed using the Life Satisfaction Index – Wellbeing. A strong and positive association was found between the two scales.
1.c Psychological measures							
Anxiety and depression according to HADS	Citizen / client	Individual level	Number	V	Questionnaire or interview	Baseline / exit	The HADS is used to determine the levels of anxiety and depression in end users. It is a 14-item scale. Seven of the items relate to anxiety and seven related to depression.
Depression according to GDS	Citizen / client	Individual level	Number	V	Questionnaire or interview	Baseline / exit	The Geriatric Depression Scale-15 (GDS-15) is a short, 15-item instrument specifically designed to assess depression in geriatric populations. Its items require a yes/no response. The Geriatric Depression Scale was first introduced by Yesavage et al. in 1983, and the short form (GDS-15) was developed by Sheikh and Yesavage in 1986.
Isolation according to Perceived Isolation Questionnaire	Citizen / client	Individual level	Number	V	Questionnaire or interview	Baseline / exit	Previous research has identified a wide range of indicators of social isolation that pose health risks, including living alone, having a small social network, infrequent participation in social activities, and feelings of loneliness. However, multiple forms of isolation are rarely studied together, making it difficult to determine which aspects of isolation are most harmful to health. Cornwell and Waite (2009) used population-based data from the National Social Life, Health, and Aging Project to generate questions combining

Measurement	Respondent / target group	Level of data	Level of detail	Mandatory/ voluntary	Preferred collection method	Timing of measurement	Reason
							multiple indicators of social isolation into scales assessing social disconnectedness (e.g. small social network, infrequent participation in social activities) and perceived isolation (e.g. loneliness, perceived lack of social support). These questions can be ascribed numerical values so that, when repeated, they provide a way for people to self-rate whether they are more or less socially disconnected and isolated from others than at the previous time of measurement.
Carer burden according to ZBI (short version)	Carers	Individual level	Number	V	Questionnaire or interview	Baseline / exit	The Zarit Burden Interview was developed to measure subjective burden among family carers of adults with dementia. Items were generated based on clinical experience with family carers and previous research, resulting in a 22-item self-report inventory that examines burden associated with functional or behavioural impairments and the home care situation. Most researchers use the 22-item version of the ZBI. However, the length of the instrument may be a deterrent to its use in clinical and research environments. Bédard et al produced a short version consisting of 12 items, with results comparable to the full version. Cronbach's α for the 12-item version is 0.88.
Carer burden according to CADI-CASI-CAMI suite	Carers	Individual level	Number	V	Questionnaire or interview	Baseline / exit	Carers are also assessed for difficulties, satisfaction and management in caring using the CADI-CASI-CAMI suite. The CADI-CASI-CAMI suite is a collection of three instruments used to assess family carers' perceptions of difficulty, satisfaction and management (coping strategies). The Carer Assessment of Difficulty Index (CADI) is a 30-item index and contains a series of statements which carers have made about the difficulties they face. Carers are asked to tick the box next to each statement that applies to them the most from the following options: 'this does not apply to me', 'not stressful', 'stressful', and 'very stressful'. The Carer Assessment of Satisfaction Index (CASI) is also a 30-item index and contains a series of statements about the satisfaction carers' experience. The Carer Assessment of Management Index (CAMI) is a 38-item questionnaire and contains a series of statements about the coping strategies used by family carers.
2. Safety							
Deaths	Citizen / client	Individual level	Yes/no (dichotomous)	M	Registries	Exit	Easy to establish, common as adverse outcome
3. End user / client / carer perspectives							
End user / client / carer empowerment	Citizen / client / carer	Individual level	Scale for each question	M	Questionnaire	Exit	Reflects the aim of SmartCare

Measurement	Respondent / target group	Level of data	Level of detail	Mandatory/ voluntary	Preferred collection method	Timing of measurement	Reason
End user / client /carer satisfaction	Citizen / client / carer	Individual level	Scale for each question	M	Questionnaire, IFIC	Exit	This would be based on the eCare Client Impact Survey developed in CommonWell and INDEPENDENT in response to a lack of instruments measuring impacts on older end-users and informal carers beyond clinical outcomes and with particular focus on impacts occurring from combined social and health care.
End user perception of integration	End-users	Individual level	One question with visual scale? Ingo, please correct me if this is wrong	M	Questionnaire	Exit	? Ingo?
4. Economic measures							
Efforts related to service development & implementation	Citizen / client / carer Service providers	Individual or organisational level	Number	M	Various	Exit Implementation and pilot phase	To support the design and implementation of viable and sustainable services. To produce supportive economic for internal decision making processes. To allow for an overall, post-hoc assessment of socio-economic impacts.
Efforts related to service operation or use	Citizen / client / carer Service providers	Individual or organisational level	Number	M	Various	Exit Implementation and pilot phase	As above.
Equipment cost	Service providers	Organisational level	Number	M	Various	Implementation and pilot phase	As above.
Service effectiveness benefits	Service providers	Organisational level	Number	M	Various	Implementation and pilot phase	As above.
Service efficiency benefits	Service providers	Organisational level	Number	M	Various	Implementation and pilot phase	As above.
Revenue streams	Service providers	Organisational level	Number	M	Various	Implementation and pilot phase	As above.
Willingness to pay	Citizen / client / carer	Individual level	Scale	V	Questionnaire	Exit	Relevant if a service fee payable by end user / client /carer is considered to become part of the revenue model.

Measurement	Respondent / target group	Level of data	Level of detail	Mandatory/ voluntary	Preferred collection method	Timing of measurement	Reason
5. Organisational impact measures							
Impacts on staff	Service providers: staff members and key informants / decision makers	Organisational level	Scales, qualitative	M	Questionnaire or interview	Pilot end	Key measures to understand the organisational changes caused by the new service, as well as to get a better understanding of what was actually achieved through the integration of different service silos. Can also capture where staff members and organisational decision makers are (still) not satisfied with the result.
Impacts on organisations	Service providers: staff members and key informants / decision makers	Organisational level	Scales, qualitative	M	Questionnaire or interview	Pilot end	As above.
Service integration aspects	Service providers: staff members and key informants / decision makers	Organisational level	Scales, qualitative	M	Questionnaire or interview	Pilot end	As above.
Mainstreaming potential and sustainability	Service providers: key informants / decision makers	Organisational level	Scales, qualitative	M	Questionnaire or interview	Pilot end	As above.
6. Possible confounders / control variables							
Date of birth	Citizen / client / carer	Individual level	YYYY-MM-DD	M	Registries or interview	Inclusion	Age is a strong predictor of any health outcome
Gender	Citizen / client / carer	Individual level	Male/female	M	Registries or interview	Inclusion	Gender is very often related to health outcomes
Level of education	Citizen / client / carer	Individual level	Categories	M	Registries or interview	Inclusion	Level of education is a strong predictor of any health outcome. Generally, it is said that one Euro given to education increases the level of health more than one Euro given to health care. Categories are important and have to be used in a similar way throughout pilots

Measurement	Respondent / target group	Level of data	Level of detail	Mandatory/ voluntary	Preferred collection method	Timing of measurement	Reason
Marital status	Citizen / client / carer	Individual level	Categories	M	Registries or interview	Inclusion	Marital status is a strong predictor of health outcomes. It is better to be married than being single. Categories are important and have to be used in a similar way throughout pilots
Ethnicity	Citizen / client / carer	Individual level	Categories	V	Questionnaire or interview	Inclusion	Ethnicity is strongly related to health outcomes
Main work status (last 12 months)	Citizen / client / carer	Individual level	Categories	V	Questionnaire or interview	Inclusion	Work status is being recognised as a strong indicator of health outcome. It turns out that people belong to the social group in which they work rather than the one in which they are educated. Categories are important and have to be used in a similar way throughout pilots
People older than 18 living in household	Citizen / client / carer	Individual level	Number	V	Questionnaire or interview	Inclusion	Indicator for the level of informal care received
Household income	Citizen / client / carer	Individual level	Number	V	Questionnaire or interview	Inclusion	Necessary if willingness-to-pay is analysed.
Daily tobacco use	Citizen / client	Individual level	Dichotomous	V	Questionnaire or interview	Inclusion	Indicator for health status
Frequency of alcohol (12 months)	Citizen / client	Individual level	Categories	V	Questionnaire or interview	Inclusion	Indicator for health status
Height (CM)	Citizen / client	Individual level	Number	V	Questionnaire or interview	Inclusion	Indicator for health status
Weight (Kg)	Citizen / client	Individual level	Number	V	Questionnaire or interview	Inclusion	Indicator for health status
Co-morbidity	Citizen / client	Individual level	ICD-10 codes	V	Questionnaire or interview	Inclusion	Indicator for health status, highly relevant for the usability of results after finishing pilots

3.4 Item 13: Time schedule of enrolment, interventions, etc. & Item 15: Strategies for achieving adequate participant enrolment

Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants & Item 15: Strategies for achieving adequate participant enrolment to reach target sample size.

Table 2: Enrolment of end users per pilot site

Expected date of first enrolee	Expected number enrolled per week	Expected finishing date of enrolling	Strategy to increase inclusion rate (1)	Strategy to increase inclusion rate (2)
Region of Southern Denmark				
May 2013	15	August 2014	Additional project management resources in the project group.	Putting pressure on leaders in the different organisations.
Aragon				
March 2014	There will be a massive inclusion of participants in three periods to ensure their participation in the project at least for 6 months.	March 2015 Living process for Discharge Pathway with a non-ending final enrolling date Living process for LTC-Pathway with a non-ending final enrolment date to cover drop-outs.	Involvement of new healthcare centres in more cities.	Involvement of new third parties associations and promotion of these services among their visitors.
Scotland				
May 2014	A detailed weekly enrolment programme has not yet been defined, although it can be extrapolated from PID document.		Accelerate contacts with and from 7 local health social care and vol providers as part of contractual requirements. Local Partnerships are responsible for participant inclusion.	Direct marketing to targeted population and their locations of interest e.g. churches, libraries as part of Communications and Dissemination Plan.

3.4.1 Further details per site

3.4.1.1 Region of Southern Denmark

In the remaining pilot phase, which runs until January 2013, the aim is to make sure that all the different types of participants are using the platform to ensure that the platform is ready for large scale implementation. The goal is to have at least 10 participants from the hospital, 3 participants from 3 different municipalities, 25 active end users and 5 different general practitioners clinics by 2014. Afterwards, the platform will be implemented more widely in the region both for heart end users in all 5 hospitals and connecting clinics and municipalities and for other relevant conditions.

The end users are asked to participate when they attend their first check-up at the hospital after discharge. Here they are both asked to participate in the research part and in using the SmartCare platform actively. All end users will be a part of the research part regardless of their use of the platform itself. The nurse in charge of the check-up is prepared to inform the end user in order for them to give their consent. She will register this consent into the SmartCare platform.

It will be the Region of Southern Denmark and the Department of Health Innovation that will be in charge of the implementation overall. In 2013 it will be the staff from both the Shared Care and the SmartCare project group; from 2014 a permanent centre is planned to be established. This centre will be in charge of support and implementation.

The participants will be divided into the intervention and control groups based on their geographic location. To make sure we have enough end users in the control group, we have selected the largest hospital in the Region (the University Hospital of Odense). This means that all heart end users in that hospital will be asked to be in the control group for six months, and afterwards be offered to be entered into the SmartCare platform.

3.4.1.2 Aragon

The starting point of this integrated-care pathway would be when an end user has been suggested to be included into the SmartCare programme, either upon a visit to Primary Care Attention or during a stay at Barbastro's Hospital.

Enrolment in ST-Pathway (Early-Discharge)

There are two ways to identify potential participants. First is during a hospitalisation of an end user. If any healthcare professional suspects that the end user is exposed to social risks of any type, then he notifies the social worker working at the Hospital. This social worker evaluates if the end user is in a real threat situation.

Enrolment in Long Term Care Pathway

Second channel would be when an end user visits a doctor at Primary Care Attention. If the GP suspects an end user to be at risk, then he refers the end user to the SmartCare Evaluation Committee who will evaluate if the user is a potential participant in the programme.

The SmartCare Evaluation Committee is the body responsible for the inclusion of participants. It is made up of SmartCare project management team (J. Coll, Dromero, ER Doctor) + 1 specialist (geriatrician) + 1 GP + 1 PC nurse + Barbastro's Hospital Social worker. It decides upon inclusion criteria (health + social needs) of the potential candidates and other requirements. This committee asks for opinions from other specialists (in charge of the end user). Local SCP will interview the end user to evaluate the social need and requirements. Acceptance by care recipient (consent form) is required.

Classification into groups

Upon identification, enrolment and acceptance, the classification of users into the control or intervention groups will be decided randomly.

3.5 Item 14: Estimated number of participants

Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations.

Sample sizes were calculated in order to avoid consequences of including more end-users than necessary into the full evaluation. Thus, the number of end-users presented in the original proposal will be reached by each participating region, whereas the evaluation will be carried out on a restricted number of end-users. This decision was primarily based on the ethical considerations of providing end-users with the 'usual care' solution after documenting the expected effectiveness of the intervention. In addition, resources are required in terms of time and money to collect and analyse data. And with enough data to establish statistical significance, further data collection would imply waste of resources related to the evaluation purposes.

3.5.1 Background: Sample size calculations in cohort studies

In randomised trials, the risk of bias due to differences in the samples receiving the intervention versus not receiving the intervention is limited due to the randomisation. The hypothesis is that randomisation ensures all possible confounding characteristics to be equally distributed in the groups of participants, and thus does not influence the results of the study (Liberati et al., 2009).

In non-randomised studies this is not the case. Therefore, a higher number of people need to be enrolled, and the calculation of sample size is more complex (Liberati et al., 2009).

In a calculation of required sample size for a cohort study, the variables include:

- α = Accepted level of significance.
- ß = Accepted level of power.
- SD = Expected standard deviation.
- Estimated change in outcome.

In order to obtain a scientifically sound estimate of outcome, a literature search was carried out in electronic bibliographic databases and in previous European projects. The search yielded a limited number of results, and there were no references focusing on integrated care which was supported by ICT. Only integration of care or ICT were identified as interventions separately.

That left two options, of which the second was chosen:

1) Make an educated guess on the change in outcome.
2) Reverse the calculations of sample size.

So, instead of assuming any undocumented change in outcome, it was decided to estimate which level of change would be acceptable in order to provide decision makers with sufficient information to decide whether or not to implement the services at a large scale.

3.5.2 Calculations

Sample size calculations were carried out for comparing two independent means with α=0.05 (level of statistical significance) and ß=0.8 (power) for two-tailed analyses (not restricting the direction of effect to be either positive or negative).

If usual care for citizens receiving services from both health and social care includes one contact per week, an average reduction of 3.6 contacts per end user for 1,000 people over

a six month period will suffice. In that sense, the outcome change is treated as the dependent variable and the number of end users as the independent.

As one strategy to determine the practical consequences of a reduction in contacts, the Danish pilot was used as a case. Since most of the staff involved in providing health and social care in Denmark are nurses, the average nurse's hourly salary (48 €) was used as the costs of one contact. 4,000 end users are considered eligible on a yearly basis for RSD and with an average reduction in contacts of 3.5, the yearly reduction in costs would be 336,000 €. An extrapolation of these results to the entire SmartCare population of 7,000 end-users would yield a total saving of 6,270,000 € annually.

With these assumptions on costs and possible savings, the calculated outcome changes were considered acceptable for decision makers.

Sensitivity analyses were carried out for varying population sizes

Table 3: Sensitivity analysis of necessary outcome for different population sizes

Sample size (including 25 % dropouts)	1000 (1250)	750 (938)	500 (625)	250 (313)
Mean contacts control group	24	24	24	24
Mean contacts intervention group	20,45	19,90	18,98	16,88
Necessary reduction in contacts	3,55	4,10	5,02	7,12

Please note: the model assumes a six month follow up and a baseline mean number of contacts during that period to be 24.

The analyses above were based on an assumption of a weekly contact during six months in the control group. In any case, the absolute necessary number of reduction in contacts does not change, if the assumed mean of contacts for control group is changed. So, if the assumption is that one contact per fortnight in the control group (=12 contacts), the necessary reduction for 1250 end users is still 3.55, for 938 end users it is 4.10 etc. It should be born in mind that the factors taken into account largely depend on the context in each individual pilot sites, so that for instance cost structures may vary from site to site.

In conclusion, all pilot sites would generally be allowed to include any number of end users, only depending on the strength of the effect to be generated. If, for example, 313 end users is the acceptable number for the pilot site, the consequence is that a reduction in contacts must reach 7.12, so that has to be a reasonable assumption in the local setting. It is also possible to calculate the specific number of end users based on what has been provided in the contract with the Commission (i.e. for 400 end users or 800 end users). Or pilots can choose to stop inclusion at 1250 or 938 end users if it is reasonable to assume a reduction of 3.55 or 4.10 contacts over the period of time.

So one aspect that pilot sites need to consider is whether it is reasonable to assume the calculated reduction in number of contacts for the number of end users eligible in the local setting.

A second aspect is that sample sizes should be high enough to allow for meaningful break-down analyses using the control variables listed in the table above. Examples would be break-downs by age group, household income or level of educational attainment. Following for example ISCED[1] for educational attainment and EUROSTAT's practice of presenting

[1] ISCED - the International Standard Classification of Education - UNESCO 1997

educational attainment levels (lower secondary = ISCED 2; upper secondary = ISCED 3c long, ISCED 3 a, b and ISCED 4; tertiary = ISCED levels 5 and 6), at least three break-down groups must be possible without n going below meaningful thresholds (~40).

Thirdly, all pilots have to agree on a similar length of time to follow up the individual end users included in order to measure the number of contacts similarly across pilot sites. This document suggests six months, which fits the SmartCare project plan nicely (six months follow up leaves six months to reach the necessary sample size). 18 months of follow-up for the first wave, and 12 months follow up for the second wave.

4. Data collection methods

4.1 Item 18a: Plans for assessment and collection of outcome, baseline, and other trial data

Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (e.g., duplicate measurements, training of assessors) and a description of study instruments (e.g., questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol.

There will be no safety measures for the data collection.

CRFs [2] will be elaborated for the common data set and common questionnaire on empowerment. Any voluntary additional measures will be recorded in local CRFs.

4.2 Item 18b: Plans to promote participant retention

Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols.

No incentives are provided for citizens or carers included in this study. End users are allowed to withdraw at any time, and will not be asked to give reasons for such decisions. (It requires specific ethical approval to ask for reasons for not wanting to participate or withdraw.) A drop-out rate of 25% has been included in the sample size calculations.

[2] Case Report Form, elaborated in section 5 for Item 19

5. Data management

5.1 Item 19: Plans for data entry, coding, security, and storage

Plans for data entry, coding, security, and storage, including any related processes to promote data quality (e.g., double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol.

A case report form (CRF) will be developed in Excel for the common dataset including variables identifying pilot site. Thus, all data should be inputted similarly throughout SmartCare. All data will be submitted to preliminary analyses before being used in statistical analyses by a predetermined strategy for missing values, odd ranges and outliers.

Security and Back-Up of Data

All data will be securely stored and backed up according to the rules and procedures followed by the respective CRF holders.

Study status reports

Status reports will be provided only after data have been collected, but on a wave basis. Thus, according to the descriptions of WP8 in SmartCare Description of Work, status reports will be provided as deliverables in work package 8 (deliverable D8.2, D8.3 and D8.4).

6. Statistical methods

6.1 Item 20a: Statistical methods for analysing primary and secondary outcomes

Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol.

6.1.1 Pilot sites

Data analyses will be carried out on the basis of each pilot site. Those analyses are described in this section.

Regression analyses will be used for the primary and secondary outcomes in analyses at local pilot site level. The types of regressions will depend on the distribution of variables being normal or not normal.

In general, the analyses will follow the principles outlined below.

The type of analyses depends on two issues:

1. The types of variables that are investigated for relationship (dichotomous, categorical or numerical); and
2. The distribution of scores for each variable (i.e. normally distributed or not).

The table below shows which kind of analyses to carry out, based on type and distribution of variables.

Table 4: Matrix of analyses (comparing groups)

Independent variable	Dependent variable	Parametric statistic	Non-parametric statistic	Essential feature
One dichotomous	One dichotomous	None	Chi-square	Identifies number of people in each category
One dichotomous	One continuous	Paired samples t-test	Wilcoxon Signed-Rank test	Same people on two different occasions
One categorical	One continuous	One-way ANOVA	Kruskal-Wallis	Three or more groups – different people in each group
One categorical	One continuous	One-way repeated ANOVA	Friedman Test	Three or more groups – same people on different occasions
Two categorical	One continuous	Two-way between groups	none	Two or more groups for each independent variable – different people in each group
One between-groups independent AND one within-groups independent	One continuous	Mixed between-within ANOVA	None	Two or more groups with different people in each group, each measured on two or more occasions
One or more dichotomous or categorical	Two or more related continuous	Multivariate ANOVA (MANOVA)	None	
One or more dichotomous or categorical AND one continuous covariate variable	One continuous	Analysis of covariance (ANCOVA)	None	

Note: The matrix is inspired by Pallant (2007; 116-117)

The table below shows the types of analyses to use when the analyses are aimed at exploring relationships among data.

Table 5: Matrix of analyses (exploring relationships)

Independent variable	Dependent variable	Parametric statistic	Non-parametric statistic	Essential feature
One dichotomous	One dichotomous	None	Chi-square	Number of cases in each category is considered
Two continuous	None	Person product-moment correlation coefficient (r)	Spearman's Rank Oder Correlation (rho)	One sample with scores on two different measures or same measure at two occasions
Two continuous and one continuous for which to control for	None	Partial correlation	None	One sample with scores on two different measures or same measure at two occasions
Set of two or more continuous	One continuous	Multiple regression	None	One sample with scores on all measures
Set of related continuous	None	Factor analysis	None	One sample multiple measures

Note: Inspired by Pallant (2007;116-117)

A final detailed strategy for analyses will be elaborated before analysing data.

6.1.2 Overall analyses

In addition to the analyses for pilot sites, a number of meta-analyses will be carried out for the primary and secondary outcomes.

The meta-analyses will be carried out as far as they are meaningful. Therefore, first the pilot sites that have similar populations will be analysed together in a meta-analysis. Next, an overall meta-analysis including the primary outcome for all pilot sites carried out in one. The current trend in scientific literature on telemedicine and telecare is presenting combined analyses across populations. For instance, WSD recently published an article presenting results of a study combining outcomes for diabetics, COPD patients and heart failure patients. Therefore, in the SmartCare project, an overall analysis will be carried out as well. The meaningfulness of this will then be discussed based on the level of heterogeneity presented in the meta-analysis.

6.1.2.1 Reporting of meta-analyses

Tables will be provided for all results, along with a graph presenting the forest plot. The interpretation of the overall effects will thus be presented in two different ways.

In addition, the I^2 (along with the designated p-value) will be reported. That is an indication of the between-study variance (heterogeneity). As a rule of thumb, if the I^2 is below 50, the studies are quite homogenous, and a fixed effects meta-analysis will be used. If the value is above 50, a random effects model will be used due to heterogeneity between studies. Although the random effects model does NOT adjust for heterogeneity, it allows the presence of it, and is thus the relevant output to present. If the heterogeneity is above 80, there is reason to discuss the appropriateness of carrying out the meta-analysis at all. Also, in these cases, a meta regression will be carried out to investigate the causes of heterogeneity.

The presentation of meta-analysis will be presented in the format of a table looking like the example below:

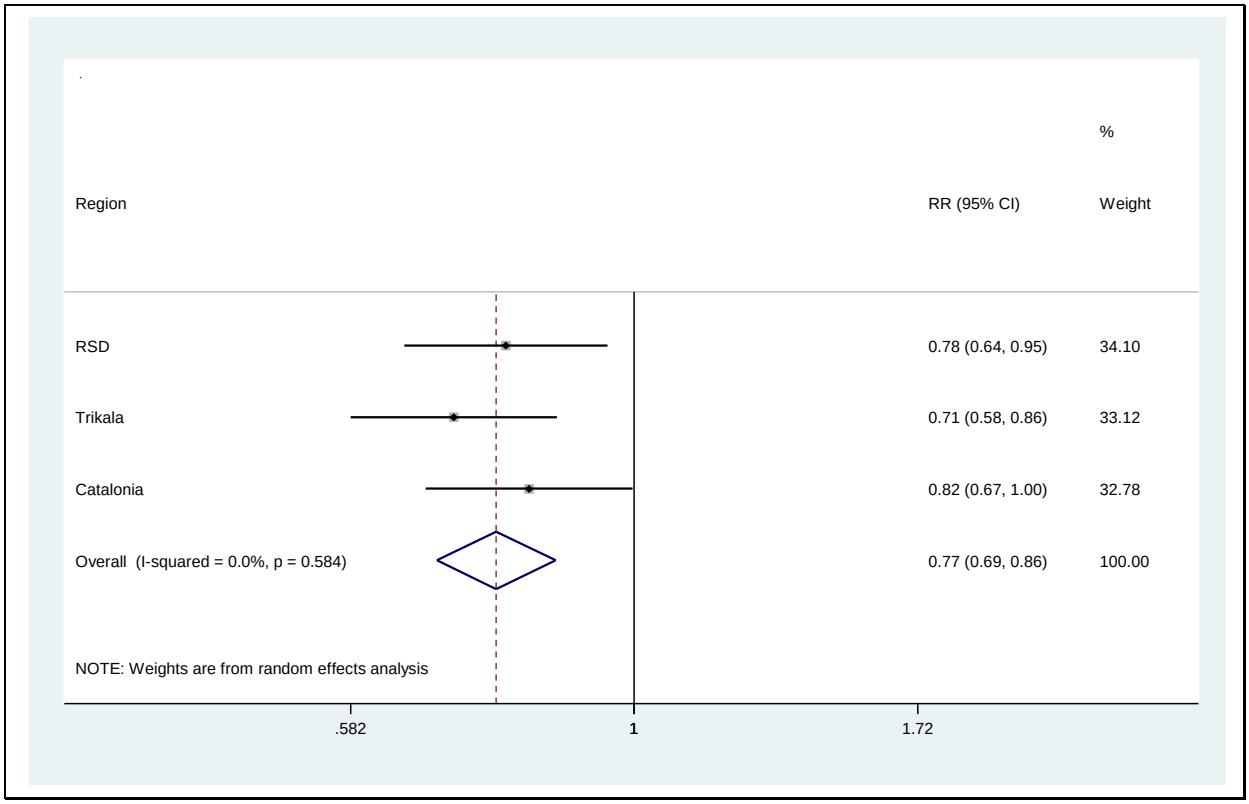
Study	RR	[95% Conf.	Interval]	% Weight
RSD	0.783	0.645	0.950	34.10
Trikala	0.708	0.582	0.863	33.12
Catalonia	0.818	0.671	0.997	32.78
D+L pooled RR	0.768	0.686	0.861	100.00

Heterogeneity chi-squared = 1.08 (d.f. = 2) p = 0.584
I-squared (variation in RR attributable to heterogeneity) = 0.0%
Estimate of between-study variance Tau-squared = 0.0000

Test of RR=1 : z= 4.56 p = 0.000

So, what the output describes is the relative risks (RR) for each setting, 95% confidence intervals (CI) and the % weight given to each study. In this simple and constructed example, all studies have positive effects, i.e. the intervention protects the patients from having an event. All effects are statistically significant. The text below the table describes the level of heterogeneity, i.e. the level of variance between the studies. The I^2 is usually reported along with the p-value. In this case, I^2 = 0.0%, p=0.5, indicating no heterogeneity (or complete homogeneity) and the homogeneity is statistically significant.

In addition to the table and explanatory text, a graph will be presented, looking like this:



For each region, the RR and confidence intervals are presented graphically. The size of the box on each horizontal line depicts the weight given to each study. Since the studies in this example are of similar size, the weights are close to equal and the boxes are of similar size. The diamond below the horizontal lines is the summary measure, i.e. the result of the meta-analysis combining the individual pilot site results. The width represents the

overall confidence interval, and the corners of the height indicate the point of the summary estimate.

6.2 Item 20b: Methods for any additional analyses

Two different approaches are planned for the overall meta-analyses. First, the pilot sites with common populations in terms of disease, frailty or other factors, will be combined in meta-analyses. Secondly, the overall meta-analysis combining results from all pilot sites will be investigated for subgroup impacts with the subgroups being based on similarities among populations.

The heterogeneity of the overall meta-analysis is expected to be high due to the differences between pilot sites. Thus, meta regressions are planned to determine whether a number of characteristics have an underlying impact on the results. Characteristics that will be used in regressions are predefined to include:

- Level of integration of services.
- Level of ICT utilisation.
- Baseline level of integration.
- Baseline level of ICT utilisation.
- Population frailty.
- Health and social care reimbursement system (level of individual payment, level of volunteer involvement).

6.3 Item 20c: Definition of analysis population

Definition of analysis population relating to protocol non-adherence (e.g. as randomised analysis), and any statistical methods to handle missing data (e.g. multiple imputation).

All analyses will be carried out on an intention to treat basis.

6.3.1 Procedure for data handling

Data cleansing requires a strategy that is clear and consistently followed in order to maintain clarity of methods. A strategy has been developed for handling errors in the data set.

Please note: Access to a codebook or description of variables in the dataset is essential for being able to perform the following process.

6.3.1.1 Categorical variables

- All observations must relate to the allowed categories.
  - If not, register the value as missing.
- The frequency distribution must make sense.
  - If not, discussion should solve issues.

6.3.1.2 Numerical variables

Missing values

- If one subject has <50% missing values, the remaining values are allowed in analyses.
  - Analyses that require some of the missing data will be run without the values, and reporting will present the total number of subjects in all analyses.
- If one subject has >50% missing values, the subject is removed from all analyses.

Outliers (histogram)

- If a value is considered to be an outlier, but the value is possible, the value will remain unchanged. In further analysis, however, sensitivity analysis will be carried out to investigate the impact of the outliers.
- If a value is an outlier, and the value is impossible, the value will be re-coded as missing.

Range check

- A value is considered illegal if it is not registered within the min-max range of possible values.
  - Illegal values are re-coded as missing.

When the described process of data cleansing has been carried out by two independent researchers, the distributions of each variable will be checked again and compared between the researchers to ensure similar results of the process. In cases of discrepancy, discussion will be reported along with chosen solution.

7. Methods monitoring

7.1.1 Item 21b: Description of any interim analyses and stopping guidelines

Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial.

No stopping rules defined. Since the SmartCare project involves only integration of services and supporting services or integration by ICT equipment, there will be no fundamental changes in the individual clinical interventions provided to people.

8. Ethics and dissemination

8.1 Item 24: Plans for seeking research approval

Plans for seeking research ethics committee/institutional review board (REC/IRB) approval.

Table 6: Ethics

Ethical considerations	Description
Plans for seeking research ethics committee/institutional review board (REC/IRB) approval.	**Region of Southern Denmark**: All end users are offered to be a part of the SmartCare platform if they are considered able to use the internet. Afterwards, a subset is extracted for evaluation purposes. The end users in the control group are offered to be entered into the SmartCare platform after six months. **Aragon**: Upon inclusion criteria **Scotland**: We will produce information and consent sheets based on the good practice guidelines above as part of the implementation process. We do not anticipate any concerns associated with these as they represent standard practice for our health and social care practitioners.
Informed consent	**Region of Southern Denmark**: The end users are offered oral and written information before giving their consent both as regards to the SmartCare platform and the SmartCare evaluation (research part). They are free to withdraw that consent at any time. The project follows the abovementioned procedures. **Aragon**: Participants are provided with an information sheet explaining the SmartCare project, its implication, what might happen etc. This information document is handled to participants by healthcare professional before their enrolment in the project. The healthcare professional will hand this document to the potential participants and/or relatives at the first meeting when proposing the inclusion, and will answer any potential question. This document is signed by the healthcare professional. Upon acceptance by the user, the end user has to hand-sign a consent document. This document reflects the user authorisation to participate in the project, and the consent to use the data for evaluation purposes. It also describes that the user can revoke consent, at any time and for any reason. Both information and consent documents are carefully written and approved by the Clinic Research Ethics Committee **Scotland**: As above.
Approval from committees	**Region of Southern Denmark**: After receiving the overall protocol, the project will be submitted to the national ethics committee. **Aragon**: Clinic Research Ethics Committee of Aragon (CEICA). **Scotland**: As we are implementing a service redesign we do not anticipate requiring Ethics Committee approval.

8.1.1 Item 31a: Plans for investigators and sponsor to communicate trial results

Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (e.g., via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions.

8.1.2 Item 31b: Authorship guidelines

Authorship eligibility guidelines and any intended use of professional writers.

Authorship will follow the Vancouver protocol.

Currently there is no intention to use professional writers.

9. References

Chan A-W, Tetzlaff JM, Gøtzche PC, Altman DG, Mann H, Berlin J, Dickersin K, Hróbjartsson A, Schulz KF, Parukelar WR, Krleža-Jerić K, Laupacis A, Moher D. SPIRIT 2013 Explanation and elaboration: Guidance for protocols of clinical trials. *BMJ* 2013;346:e7586.

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Pallant J. 2007. *SPSS Survival manual. A step by step guide to data analysis using SPSS*. Allen & Unwin: Australia

Vancouver protocol:
http://www.research.mq.edu.au/about/research_@_macquarie/policies,_procedures_and_conduct/documents/Vancouver.pdf, visited on September 3rd 2013.

10. Appendices

10.1 Item 32: Model consent form and other related documentation given to participants and authorised surrogates.