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Study protocol of a non-randomised controlled trial evaluating the effectiveness of the F@ce 2.0 programme: a person-centred, ICT-supported and interdisciplinary rehabilitation intervention after stroke

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ABSTRACT

Introduction Knowledge is missing on use of information and communication technology (ICT), for example, mobile phones/tablets in rehabilitation after stroke. F@ce 2.0 is a person-centred, interdisciplinary intervention supported by ICT. The components of F@ce 2.0 intend to increase performance in daily activities and participation in everyday life for patients with stroke and their significant others. Based on previous feasibility studies, a full-scale evaluation is planned in Sweden. The aim is to implement and evaluate F@ce 2.0, regarding performance of daily activities and participation in everyday life, in comparison with ordinary rehabilitation among persons who have had stroke and significant others. Second, to increase knowledge about how the programme leads to a potential change by studying the implementation process and mechanisms of impact.

Methods and analysis Twelve rehabilitation teams (intervention n=7; control n=5) will recruit patients (n=160) who receive rehabilitation at home after stroke and their significant others. F@ce 2.0 is an 8-week intervention where patients, together with the team, formulate three activity goals regarding what they need and want to do in daily lives. The patients will receive short messages service (SMS) each morning reminding about goals, and in the evening to rate their performance during the day. Primary outcomes for patients: self-efficacy measured by the Self-Efficacy Scale; perceived performance in daily activities measured by the Canadian Occupational Performance Measure. Significant others: perceived caregiver burden measured by Caregiver Burden Scale. Qualitative interviews with team members delivering, patients receiving intervention and significant others will explore experiences of F@ce 2.0. A process evaluation applying a case-study design using mixed methods will be conducted.

Ethics and dissemination Approved by the Swedish Ethical Review Authority, Stockholm. Knowledge will be created for using ICT for rehabilitation of people after stroke in self-selected activities. Dissemination will include peer-reviewed publications, presentations at conferences, and information to stakeholders.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The study is a full-scale trial with a nested process evaluation of a theory based, and feasibility tested rehabilitation intervention after stroke.
⇒ Different stakeholders were involved in the development of the research project highlighting several perspectives.
⇒ A limitation is the non-randomised design of the trial.

Trial registration number details NCT04351178.

INTRODUCTION

Stroke is one of the major public health diseases internationally and in Sweden. The Swedish National Board of Health and Welfare reported that in 2017 approximately 25 800 people had had stroke.[1] For survivors, stroke often leads to decreased functioning in everyday life due to impairments, activity limitations and participation restrictions. In addition, significant others are at risk of depression, caregiver burn-out, isolation and decreased life satisfaction.[2] Changes in everyday life may, therefore, occur for the persons who have had a stroke and their families[3] and there is often a need for rehabilitation. In previous studies, being involved in engaging daily activities has been shown to contribute to a positive change in the recovery process.[4] Engaging activities contribute to an intense feeling of participating in activities and a sense of meaning and purpose which make life worth living.[5] Creating experiences of performing daily activities in the rehabilitation process after stroke is important since successfully performed activities will

strengthen a sense of self-efficacy, that is, belief in one's capability to perform activities. The stronger the belief in one's self-efficacy (in performing an activity), the more likely the person is to initiate and persist in engaging in that activity.[6 7] Increased self-efficacy can be realised by, for example, goal setting, knowledge building and problem-solving strategies.[8] Empirical studies in rehabilitation after stroke have shown the positive effects of activities of daily living (ADL) interventions,[9] and home-based ADL-training is also highly prioritised in the Swedish National Board of Health and Welfare's guidelines for stroke care.[1] Nonetheless, research about how rehabilitation interventions can enable daily activities and participation in everyday life after stroke is limited.

It has been reported that people in contact with Swedish health services are largely viewed as recipients of services rather than as cocreators of their rehabilitation.[10] Rehabilitation often fails to anticipate and respond to patients as individuals with particular needs, values, and preferences.[11] Further, the Swedish Agency for Health and Care Services Analysis emphasises that adhering to Swedish Patient Act means implementing person-centred healthcare and increasing the extent to which people participate in decisions regarding their own health.[12 13] Despite a strong emphasis on person-centredness in rehabilitation internationally and nationally, scientific knowledge is limited on how it can be achieved.

Digital technology, including information and communication technology (ICT), has rapidly developed and might offer opportunities to access and use rehabilitation more efficiently.[14–16] Digitalisation in society and people's increased use of ICT, such as mobile-phones-based and internet-based services, have influenced their engagement in social activities as well as activities at home, work and in public places.[17 18] Mobile phone technology has been experienced to increase the quality and extend the reach of rehabilitation .[14 19] The use of ICT can also have an impact on the United Nations Agenda 2030, the Sustainable Development Goals (SDGs). The SDG on Health is to 'ensure healthy lives and promote well-being for all at all ages', which might be facilitated using mobile technology. There may also be disadvantages with digital technologies, which are often criticised as not suitable for all and not for those who have the greatest need for rehabilitation. For example, although cognitively impacted persons may have difficulty using a mobile phone,[20–22] some studies have shown the opposite.[23 24]

Our previous qualitative studies have highlighted the importance of including the person's perspective as the point of departure for interventions. People with stroke get 'significant experiences that contribute to change' by doing activities that they want and appreciate during rehabilitation.[4] The F@ce 2.0 intervention that will be evaluated in this study was developed gradually. At first, a client-centred rehabilitation programme was developed by researchers from the HELD group (https://ki.se/en/nvs/health-in-everyday-life-among-people-with-neurological-disorders-held) at Karolinska Institutet to enable such significant experiences.[4 25 26] The knowledge base was grounded in the voices of people with stroke and healthcare professionals from our previous studies,[4 27–29] and in theories on occupation and client-centredness/person-centredness.[30–32] In F@ce 1.0 the client-centred rehabilitation programme, provided by occupational therapists in rehabilitation teams, was further developed both in Sweden and Uganda by researchers from the HELD group into an interdisciplinary intervention supported by ICT, such as mobile phones and/or tablets. Digital support is a web platform that sends SMSs with reminders to patients and renders it possible for healthcare professionals to monitor the rehabilitation process. Our feasibility studies on F@ce 1.0 have shown that the intervention can support rehabilitation after a stroke and has the potential to increase self-efficacy and satisfaction with activity performance among users.[24 33] In F@ce 2.0, we will evaluate the person-centred, interdisciplinary and ICT-supported rehabilitation intervention in a full-scale trial. The F@ce 2.0 programme includes the following parts: (1) an online education workshop for rehabilitation teams, (2) a person-centred, goal-directed ICT-based intervention for patients who have had stroke and (3) a web-based platform that sends daily SMSs to patients, with (A) reminders on activity goals in the morning and (B) follow-up SMSs in the evening to which the patients respond with a rating on their performance during the day. The teams have access to these ratings and the web-platform thereby supplies a two-way communication.

Objectives

The overall aim of this project is to implement and evaluate F@ce 2.0, a person-centred, ICT-supported and interdisciplinary rehabilitation intervention regarding performance of daily activities and participation in everyday life, in comparison with ordinary rehabilitation among persons who have had stroke and their significant others.

The second aim is to increase knowledge about how F@ce 2.0 leads to a potential change by studying the implementation process and mechanisms of impact of the programme.

Research questions

1. Are there any differences in effects at inclusion, directly after the 8-week intervention and at the 6-month follow-up among persons who have had stroke and participated in the F@ce 2.0 intervention or in ordinary rehabilitation regarding (A) self-efficacy, (B) perceived performance in daily activities and participation in everyday life and (C) independence in ADL?
2. Are there any differences at inclusion, after completed intervention and at the 6-month follow-up between the significant others of persons receiving the F@ce 2.0 intervention in comparison to the significant others of those receiving ordinary rehabilitation regarding caregiver burden, provision of informal care, mood and life satisfaction?

3. How do persons who have had a stroke and their significant others experience their participation in the F@ce 2.0 intervention?
4. How can the outcomes of the F@ce 2.0 intervention be explained taking the implementation process and potential mechanisms of impact into consideration?

METHODS AND ANALYSIS

Trial design

This protocol follows the Standard Protocol Items: Recommendations for Interventional Trials 2013 statement.[21 22] A non-randomised controlled design has been chosen to compare the outcome in participants receiving F@ce 2.0 along with ordinary rehabilitation that is, the intervention group (IG), with the outcome in participants receiving only ordinary rehabilitation, that is, the control group (CG). The non-randomised controlled design was chosen due to the COVID-19 pandemic which significantly challenged Swedish healthcare services and made the originally planned cluster randomisation impossible. Nested qualitative studies and process evaluation will be conducted as recommended by the Medical Research Council (MRC) guidance.[34]

Study setting

Interdisciplinary home and neurorehabilitation teams at units located in the three healthcare regions of Stockholm, Gävleborg and Dalarna will be recruited to deliver Face 2.0 or ordinary rehabilitation. Home and neurorehabilitation teams with the possibility to participate in preparatory workshops will be included in the IG to deliver F@ce 2.0 whereas teams without the possibility to participate in the workshops will be the CG and deliver ordinary rehabilitation. The team members will include occupational therapists and physiotherapists. Other professions are nurses, speech and language therapists, medical social workers, physicians, dietitians, and assistant nurses. Like most healthcare services in Sweden, this rehabilitation is publicly funded.

Participants: eligibility criteria

Three categories of participants will be included: patients with stroke, significant others, and members in the rehabilitation teams. Patients with stroke will be included if they fulfil the following inclusion criteria: (A) diagnosed with stroke, (B) enrolled in one of the participating units, (C) able to participate in 8 weeks of intervention, (D) ability to formulate and express activity goals in Swedish or with an interpreter's assistance and (E) self-reported ability to use a mobile phone. A significant other, a person identified as close to the patient by the patient themselves will be included. Finally, team members who have participated in the workshops and delivered the intervention will be included.

The F@ce 2.0 programme

Workshops for providers of F@ce 2.0

The teams assigned to deliver F@ce 2.0 (IG; n=7) within the Stockholm, Gävleborg and Dalarna regions will receive online education by the researchers. The education will be organised with blended learning in four workshops, one occasion per week, at time points convenient for the teams. The duration of the workshops will be 8 hours in total. The team members will have assignments in between workshops, requiring approximately 2 hours work. The workshops will be organised so that teams from different regions meet digitally for discussions and reflections on F@ce 2.0. The members of the rehabilitation teams (approximately 6–10 team members from each team) will receive information regarding the basic principles, the theoretical and empirical underpinnings of F@ce 2.0, and the use of ICT as a tool in rehabilitation. During the workshops, the team members together with the researchers will discuss and reflect on person-centred rehabilitation after stroke. Further, in the workshops the teams will have room to reflect on their own ways of working and how to integrate F@ce 2.0 in their teamwork. As reflection on clinical practice is seen as essential in developing and maintaining competence, as well as integrating research knowledge in practice,[35] a model including critical reflection has been chosen for the workshops.[36]

After the last workshop, all team members will receive a keep-in-mind-card with the components of F@ce 2.0 and a checklist for delivering the intervention. The F@ce 2.0 web platform will contain information on stroke, theories and concepts underlying the intervention to enable the team members to reflect on the content of the intervention and for the researchers to share information. The teams delivering the intervention will have weekly digital meetings/telephone calls with a contact person in the research team during the study period to support the teams and monitor the intervention delivery.

The F@ce 2.0 intervention

The F@ce 2.0 intervention will be provided to patients as a supplement to ordinary rehabilitation. F@ce 2.0 is a person-centred, ICT-supported, interdisciplinary 8-week intervention using goal setting and problem-solving strategies. Two general strategies are combined and should be used by the teams (ie, during the entire intervention process) in order to enable change: (1) using the person's lived experience as a point of departure and (2) enabling significant experience to be gained from performing valued daily activities. The identified components of F@ce 2.0 (see online supplemental figure 1) aiming to increase performance in daily activities and participation in everyday life for patients who have had a stroke and their significant others. The participants formulate three activity goals, that is, what they want and need to do in their daily lives using the Canadian Occupational Performance Measure (COPM).[37] Based on the set activity goals, a problem-solving strategy will be used when the patient, together with the team, formulate strategies for how the goals will be met. Participants will practice the activities at home with support via daily SMS reminders.

The web-based platform in F@ce 2.0

One of the team members will register the goals and strategies into the F@ce 2.0 web platform. The platform will then send SMS messages or e-mails to participants each morning to remind them of the activity goals. Every afternoon the participants will receive a follow-up SMS in which they are asked to, in a reply SMS, rate their performance (from 1 to 5) of the activities set as goals. The team members will see the daily ratings via the F@ce 2.0 web platform and provide support if needed. Low scores (1–2) will be marked red in the system to alert the team to contact the participant. An average of 3 will be marked with yellow and high scores (4–5) marked with green, indicating no need to contact the participant.

Outcome data

All data collected from patients and their significant others will be self-reported. Primary outcomes for patients are self-efficacy in performing daily activities, that is, confidence in one's own ability measured by the Self-Efficacy Scale[38 39] and perceived performance in daily activities measured by the COPM.[37] The primary outcome for significant others will be their perceived burden of caring using the Caregiver Burden Scale.[40] Secondary outcomes for patients will be the Stroke Impact Scale 3.0 (SIS 3.0),[41] Katz Extended ADL Index,[42] Barthel Index,[43 44] Fatigue Severity Scale-7[45 46] and Frenchay Activity Index (FAI).[47] Two secondary outcomes will be used for both patients and significant others; Hospital Anxiety and Depression Scale[48]; and Life Satisfaction Questionnaire (LiSat-11)[49]

Participant timeline

Participant enrolment will be initiated in year 1 and the last follow-up is scheduled at year 3. The study timeline is presented in table 1.

Sample size and power considerations

Power calculations based on the results from the feasibility study in Uganda[33] on the primary outcome self-efficacy and accommodating for an attrition rate of 10% showed that 80 participants is required in each group, in total n=160, (alpha set at 0.05 and beta at 0.80). Power to detect a clinically important difference of 2 points in the secondary outcome COPM, will require 40 participants in each group. The results will be reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) 2010 Statement[50] and the CONSORT 2010 Extensions for pragmatic trials in healthcare.[51]

Recruitment and informed consent

The rehabilitation teams will identify potential study participants (patients), inform them verbally, provide written information about the study and ask for permission to forward their contact information to the principal investigator. The potential participant will then be contacted by telephone for verbal information about the study and an opportunity to ask questions prior to giving verbal informed consent. Written information, an informed consent form and a prestamped envelope will be sent by mail. Patients who consent to participate will be asked to identify a significant other (ie, wife, husband, friend, daughter) who will receive verbal and written information about the study and informed consent will be obtained according to the same procedures presented above. Patients who do not have, or choose not to identify a significant other, will remain in the study. Patients who decline to participate in the study will receive ordinary rehabilitation.

Data collection

All data will be collected digitally by experienced and trained research assistants blinded to which teams will provide F@ce 2.0 in addition to ordinary rehabilitation and those that will not. Demographic data will be collected at baseline for both the CG and IG including age, gender, living conditions, need of assistance and use of ICT (see table 1). Baseline assessments will be conducted during the first week after enrolment and follow-up assessment will be performed 1 week after F@ce 2.0 has ended. Follow-up will also be conducted 6 months after inclusion. Designated researchers with experience in collecting qualitative data will conduct the qualitative interviews.

Primary outcomes

Patients

Self-Efficacy Scale assesses self-efficacy, that is, confidence in one's own ability.[38 39] Self-efficacy is based on Bandura's social cognitive theory[38] and assesses the person's belief in his/her capability to perform activities and realise a desired result. The theory of self-efficacy suggests that the stronger a person's efficacy expectations are, the more probable it is that they will initiate and continue with given activities. The patients will be instructed to rate how confident they are about performing each of the 18 everyday activities on a 10-point rating scale ranging from 1) 'not being confident at all in my ability' to 10) 'being very confident in my ability'.[52] The Self-Efficacy Scale has been adapted for people with stroke.

COPM assesses the person's own perceptions of performance and satisfaction in valued activities in everyday life within the areas of self-care, productivity and leisure.[37] The person rates the importance of being able to perform each activity on a 10-point scale. Thereafter the person is asked to choose three activities relevant to them and to rate their own performance and satisfaction with the performance of each activity on separate scales. A higher score reveals greater importance, better performance and greater satisfaction. A difference of two points or more between ratings indicates a clinically significant change.[37]

Significant others

Caregiver Burden Scale measures the perception of burden among the persons that assist/care for a person with stroke.[40] The areas in the scale deal with the caregiver's health, general strain, isolation, disappointment, emotional involvement and environmental aspects. The

Table 1 Participant timeline and data collection

	Enrolment	Post allocation			
Time-point	0 week	Weeks 1–8	Week 9	6 months	After last patient completed
Enrolment					
Eligibility screening	X				
Informed consent	X				
Interventions					
F@ce 2.0		X			
Control: ordinary rehabilitation		X			
Data collection patients					
Demographics	X				
Self-efficacy Scale	X		X	X	
Canadian occupational performance measure	X		X	X	
Stroke Impact Scale 3.0	X		X	X	
Frenchay Activity Index	X		X	X	
Barthel Index	X		X	X	
Katz Extended Activities of Daily Living	X		X	X	
Fatigue Severity Scale-7	X		X	X	
Hospital Anxiety and Depression Scale	X		X	X	
Life Satisfaction Checklist	X			X	
Qualitative interviews			X	X	
Survey regarding intervention			X		
Significant others					
Demographics			X		
Caregiver Burden Scale			X	X	
Hospital Anxiety and Depression Scale			X	X	
Life Satisfaction Checklist			X	X	
Qualitative interviews			X	X	
Survey regarding intervention			X		
Team members and researchers					
Qualitative interviews			X		X
Team members' registrations on the web platform*		X			
Researchers' notes from weekly team contact		X			
Teams' logbooks*		X			

*Team members register on the web platform and update the logbooks continuously until all patients have completed the F@ce 2.0 intervention.

22 items are scored from 1 to 4 (not at all, seldom, sometimes, often) and a lower score indicates low perceived burden.

Secondary outcomes

Patients

The perceived impact of stroke will be assessed with the SIS 3.0[41] containing eight domains: strength, memory and thinking, emotions, communication, ADL/Instrumental ADL (IADL), mobility, hand function and participation. Self-reported frequency of performance in social activities and everyday activities in the areas of domestic chores, leisure/work and outdoor activities will be assessed with the FAI.[47] Dependence/independence in 10 self-care and mobility activities will be assessed with the Barthel Index.[43 44] The Katz Extended ADL Index will be used to assess dependence/independence in six personal ADL activities and in four IADL activities.[42 53] The Fatigue Severity Scale-7 will be used to assess fatigue .[45 46]

Patients and significant others

Mood, divided into anxiety and depression, will be assessed with the Hospital Anxiety and Depression Scale[48]; and life satisfaction with the LiSat-11 which measures life satisfaction globally and in ten domains.[49]

Experiences of F@ce 2.0 among patients and significant others

Semistructured interviews conducted via digital meeting services or by phone will be performed. Interviews with patients from each region's IG (n=15–20) and their significant others (n=15–20) will be conducted after participation in F@ce 2.0 is completed and 3 months thereafter. To obtain rich data the participants will be selected with a variation in sex, level of disability (among patients) and living conditions. An interview guide with open-ended questions will be used focusing on experiences of participating in F@ce 2.0 and on the participants' experiences of everyday life.

Process evaluation of F@ce 2.0

The process evaluation will apply a single-case study design using mixed methods. The MRC guidance recognises the value of process evaluation within trials, stating that it can be used to assess fidelity and quality of implementation, clarify causal mechanisms and identify contextual factors associated with variation in outcomes.[54] In this study, the process evaluation includes semistructured interviews with patients, significant others, researchers and team members. Furthermore, field notes and quantitative process data will be included to capture data on the implementation, context and mechanisms of impact[54] as presented in table 2.

Information about how stroke rehabilitation is organised in each of the three regions will be collected in interviews with team members and from regional stroke guidelines. The implementation of F@ce 2.0 will also be viewed from the perspective of providing or receiving the intervention in an urban or rural context in all participating regions to explore differences in accessibility.

The different data collection methods used in the process evaluation are presented in table 2.

The semistructured individual interviews with patients from the IG and their significant others, regarding their experiences of participating in F@ce 2.0 (conducted

Table 2 Data collection in the process evaluation

The process evaluation				
To evaluate the impact of:		Context Factors external to the intervention which may influence its implementation, or whether its mechanisms of impact act as intended.	Implementation process Fidelity—the consistency of what is implemented with the planned intervention dose—how much intervention is delivered reach—the extent to which the target audience comes into contact with the intervention.	Mechanism of impact participant responses—how they interact with the intervention Mediators—intermediate processes which explain subsequent changes in outcomes Unintended pathways and consequences.
Methods used:				
Individual semistructured interviews				
	Patients		X	X
	Significant others	X		X
	Team members	X*	X	X
	Researchers	X		X
Focus groups interviews				
	Team members		X†	
Questionnaires				
	Patients		X‡	X
	Significant others		X‡	X
Web platform				
	Patients		X	
	Team members		X	
Researchers' weekly logbooks		X	X	X
Inclusion/exclusion protocol			X	

*Semistructured interviews will be conducted with team members in each of the participating rehabilitation teams (in total n=15). A purposive sampling of all participants will be used to ensure rich data and variation.
†Focus group interviews with team members will be conducted after they have experienced applying F@ce 2.0 in clinical practice and once all patients have completed the intervention.
‡Self-reported questionnaires to patients and significant others regarding involvement and assistance in the intervention will be conducted at the 9-week follow-up.

postcompletion as described above), will also be used in the process evaluation.

All interviews will be digitally recorded and transcribed verbatim. All personal data will be eradicated (ie, names) during transcription. Copies of the digital recordings will be destroyed after transcription has been completed. All data will be coded and stored on a secure electronic database.

Data analyses

The characteristics of all patients at inclusion, and outcomes at 9 weeks and 6 months after inclusion, will be presented with descriptive statistics. Intention-to-treat analysis will be used when comparing the primary and secondary outcomes between the IG and CG. Differences in change over 6 months between the IG and CG will be analysed with mixed models, considering plausible confounders. The number of participants recruited (patients/significant others) will be presented in a flow chart. The retention rate and adherence to F@ce 2.0 for example, responses to the SMSs and the number of participants seen by each team, will be presented based on frequencies and percentages. Analyses of the individual interviews regarding experiences of participating in F@ce 2.0 will be analysed using a grounded theory approach, while the qualitative data used in the process evaluation will be analysed with content analysis.

Evaluation of outcomes

The patient's perceived confidence in performing common everyday activities will be presented based on the Self-Efficacy Scale scores ranging from 1 to 10.[38 39]

The patients' change in perceived performance and satisfaction of their stated valued activities will be presented based on the COPM scores.[37] The summative scores will be divided by the number of rated activities to provide COPM scores for comparisons across time and between groups.

All data regarding impact of stroke, participation in and performance of activities, fatigue, mood and life satisfaction from the persons who have had a stroke will be analysed and reported according to the norms of the measurements. So too will the data from the outcome measures used with the significant others.

Experiences of F@ce 2.0 among patients and significant others: qualitative interviews: Data analysis of interviews will apply a grounded theory approach[55] to present a meaning structure comprising a core category and subcategories of the findings (ie, the experiences of participating in Face 2.0 and of everyday life after stroke).

Process evaluation of the implementation: qualitative interviews and process data: A mixed-method approach where qualitative and quantitative data are integrated will be used to answer how the implementation process and potential mechanisms of impact can explain the outcomes of F@ce 2.0. Content analysis in accordance with Graneheim *et al*[56] will be used to analyse the semi-structured interviews from the participants with stroke, significant others, and team members. The quantitative data will be analysed using descriptive statistics. Data on implementation, context and mechanism of impact from different data sources, but with a counterpart relationship, will be analysed separately and thereafter integrated in a joint analysis to explore the relationships between the findings. Data analysis on context will be guided by the context component in the integrated Promoting Action on Research Implementation in Health Services.[57]

Patient and public involvement

Data from the Stockholm region feasibility study were used as part of modelling the intervention. The researchers also met the team members several times to listen to experiences from their everyday work. This informed the formulation of research questions, as well as the design and delivery of the research project. The results of this study will be presented to various stakeholders, regionally and nationally.

DISCUSSION

The Swedish Health and Social Care Inspectorate (IVO) has identified flaws regarding the person-centredness and coordination of care in the Swedish healthcare system.[58] IVO concludes that there is a need to enhance person-centred care, that is, to involve patients in their own care. IVO furthermore proposes the development of digital tools that are simple and usable for communication and follow-ups in interprofessional teamwork.[58] The proposed study will implement and evaluate a rehabilitation programme in which these identified needs and knowledge gaps will be addressed.

F@ce 2.0 may provide an opportunity for digital support in rehabilitation in everyday activities for people with stroke. This is in line with the Swedish government's vision to be world leading in digital health solutions by 2025.[59] Digital tools can be of particular relevance for use when there is limited access to rehabilitation due to long distances to healthcare. Therefore, from an equity perspective it is imperative that research is not only conducted in urban areas for example, in Stockholm but also beyond the largest cities in Sweden.

It is expected that this non-randomised controlled study including a process evaluation will provide information on effects and aspects related to the perceived value and acceptability of F@ce 2.0; fidelity, reach and dose for future use in clinical practice.

ETHICS AND DISSEMINATION

This study has been approved by the Regional Ethical Review Board in Stockholm, Sweden Numbers 2013/1801-31, 2017/1420-32 and with a supplement 2020-01124 by the Swedish Ethical Review Authority.

The rehabilitation teams will inform potential study participants verbally and provide them with a brochure with information about the study. The team will then ask for permission to forward the person's contact

information to the principal investigator. Those who accept will be contacted by telephone by the principal investigator who will give verbal information about the study. Additionally, they will ensure that potential participants have gained an understanding of the information provided, including that participation is voluntary and that they have a right to withdraw at any time. A written information and informed consent form will be sent by mail, including a prestamped envelope. The signed, informed consent is then to be mailed back to the principal investigator. Patients who consent to participate will be asked by the principal investigator to identify a significant other (ie, wife, husband, friend, daughter) who will receive verbal and written information about the study. Informed consent will thereafter be obtained according to the same procedures presented above.

Each participant (person with stroke, significant other, team member) will receive an ID number. Therefore, the analysis and the results will be performed and presented confidentially. It is not expected that taking part in the study will be associated with risks or complications, but all adverse events, for example, falls will be asked for in the follow-ups.

The project is planned to include delivery of several scientific publications in open access peer-reviewed journals and presentations at national and international scientific conferences. In addition, the findings will be reported to the funder as well as to healthcare and policy stakeholders in the regions involved. Study participants will be informed of the study findings in newsletters from the project group. Results will be presented to patients with stroke and their significant others in meetings and popular science publications organised by patient organisations, and in profession-specific periodicals.

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Contributors SG, GE, CY and LvK conceived the original idea and outline of the study. SG, GE, CY, LvK and MT contributed to designing the study. SG has been responsible for developing the intervention in collaboration with CY and GE. UF is responsible for the technical development and digital tools used in F@ce 2.0. SG, GE and MT are responsible for collaboration with the regions taking part in the study, and for training and monitoring the home rehabilitation teams together with the research assistants. SG and GE drafted the study protocol which was further developed in an iterative process involving MT, LvK, CY and ME. All authors have commented and approved the final version. Authorship for future studies stemming from the main trial will be discussed between the authors of the study protocol and decisions will be based on the authors' contributions.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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