Psychosocial well-being after stroke

Evaluating the effect of a complex intervention aiming to promote psychosocial well-being after stroke

A multicentre randomised controlled trial
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Abstract

Background—Psychosocial challenges are frequent after stroke and can affect motivation, long-term functioning and quality of life and reduce the effects of rehabilitation. There is a tendency to focus on treating physical symptoms in stroke rehabilitation, while systematic psychosocial rehabilitation is more rarely part of rehabilitation after stroke in the healthcare services in the community in Norway. Due to the consequences of post-stroke psychosocial problems, psychosocial well-being should be considered an important outcome in stroke rehabilitation. However, previous studies have not provided a clear recommendation of how to address these challenges that is effective and feasible in a Norwegian community setting.

Aims—The overall aim of this dissertation was to evaluate the effect of a previously developed and feasibility-tested psychosocial intervention on well-being after stroke in a multicentre randomised controlled trial (RCT). The purpose of the first sub-study was to explore the psychometric properties of the primary outcome measurement of the RCT, the General Health Questionnaire-28 (GHQ-28), when applied in a stroke population. The second sub-study aimed to evaluate the effect of the dialogue-based intervention on psychosocial well-being six months after stroke. The third sub-study evaluated the potential effect of the intervention on psychosocial well-being one year post-stroke.

Method—Adults (≥ 18 years) who were within one month post-stroke were included. All participants received usual care that included admittance to acute stroke units followed by further treatment and therapy in rehabilitation centres or in the municipality, according to their needs and the availability of services. The participants in the intervention group received a dialogue-based intervention in addition to the usual care during the period between one and six months post-stroke.

The dialogue-based intervention
The intervention targeted the participants’ feelings, thoughts and experiences after the stroke and consisted of eight individual one- to one-and-a-half-hour sessions between the participant and a trained healthcare professional (a registered nurse or an occupational therapist). Each meeting had a guiding topical outline addressing significant issues described in the research literature, such as bodily changes, emotional challenges, personal relationships, daily life issues, meaningful activities, existential issues and important values.

Statistics
The primary outcome measurement was the General Health Questionnaire-28 (GHQ-28). The secondary outcome measurements included health-related quality of life (Stroke and Aphasia Quality of Life scale (SAQOL-39g)), sense of coherence (SOC-13) and depression (the Yale–Brown single-item questionnaire).

The factor structure of the GHQ-28 was evaluated by exploratory factor analysis (EFA), and a confirmatory factor analysis (CFA) was used to determine the goodness of fit to the original structure of the outcome measurement and measurement invariance. To explore the effect of the intervention, logistic regression, general linear modelling, independent-sample t-tests and paired-sample t-tests were applied to the data analysis at six months. For the analysis of the 12-month data, a linear mixed model (LMM) analysis was used to assess the primary outcome of psychosocial well-being at 12 months post-stroke and to explore predictors influencing the GHQ-28 scoring.

Results—A higher level of sense of coherence had a protective effect on a lower level of psychosocial well-being, but addressing psychosocial challenges did not strengthen the participants' sense of coherence or psychosocial well-being.

Sub-study I: Construct validity was not confirmed, and sub-factor analysis based on the original factor structure of the GHQ-28 should be interpreted with caution. The factor composition is assumed to be affected by characteristics in the stroke population. Exploring the factor composition in the population in which sub-factor analyses of the outcome measurement are planned is recommended prior to statistical analysis.

Sub-study II: Psychosocial well-being improved during the first six months after stroke in both arms of the trial, but a statistically significant benefit of the dialogue-based intervention in addition to standard stroke care was not found.

Sub-study III: The results did not demonstrate that the participants in the intervention group experienced higher levels of psychosocial well-being and health-related quality of life and lower levels of depressive symptoms and anxiety than participants in the control group at 12 months post-stroke. Participants reporting caring responsibilities, fatigue, depressive symptoms and additional comorbidities were prone to a lower level of psychosocial well-being.

Conclusions—Psychosocial well-being improved during the first year post-stroke. Most improvement occurred from one to six months after stroke. Several vulnerable groups at risk for developing psychosocial challenges were identified, but a benefit of the dialogue-based intervention compared to standard stroke treatment in these groups was not found in the statistical analyses.

Because of the complexity of the setting and challenges with the validity of the primary outcome, it is difficult to pinpoint what factors are the most important in promoting psychosocial well-being one year after stroke. This dissertation discusses possible reasons for the results of the trial.

Sammendrag

Bakgrunn—Psykososiale utfordringene er vanlig etter hjerneslag og kan påvirke motivasjon, funksjon, livskvalitet samt redusere effekten av rehabilitering. I opptreningen etter slaget er det en tendens å vektlegge behandling av fysiske konsekvenser, mens systematisk psykososial rehabilitering sjelden er inkludert som en del av behandlingen etter hjerneslag i kommunehelsetjenesten i Norge. På grunn av konsekvensene av psykososiale problemer, bør psykososial helse anses som et viktig mål i slagrehabilitering. Tidligere studier har ikke gitt en klar anbefaling om hvordan best møte de psykososiale utfordringene på en måte som både er effektiv og gjennomførbar i kommunen.

Mål—Det overordnede målet i denne avhandlingen var å evaluere effekten av en tidligere utviklet og utprøvd intervensjon for å fremme psykososial helse etter hjerneslag. Formålet med den første del-studien var å utforske de psykometriske egenskapene til det primære måleinstrumentet i RCTen, General Health Questionnaire-28 (GHQ-28), når det anvendes i en slagpopulasjon. Formålet til den andre del-studien var å vurdere effekten av den dialogbaserte intervensjonen for å fremme psykososial helse seks måneder etter slaget. I den tredje del-studien, var målet å evaluere eventuell effekt av intervensjonen for å fremme psykososial helse ett år etter slaget.

Metode—Voksne deltakere (≥ 18 år) ble inkludert inntil en måned etter slaget. Alle mottok vanlig slagbehandling som inkluderte sykehusinnleggelse, etterfulgt av ytterligere behandling ved et rehabiliteringssenter eller i kommunen ut fra behov og tilgjengelighet av tjenester. Deltakerne i intervensjonsgruppen mottok i tillegg en dialogbasert intervensjon som supplement til den vanlige behandlingen i tidsrommet en til seks måneder etter slaget.

Den dialogbaserte intervensjonen
Intervensjonen var rettet mot deltakernes følelser, tanker og erfaringer knyttet til livet etter slaget og bestod av åtte individuelle 1-1 ½ timers møter mellom deltaker og helsepersonell (sykepleier eller ergoterapeut). Møtene tok utgangspunkt i ulike tema basert på vanlige utfordringer etter hjerneslag beskrevet i litteraturen, som kroppslige endringer, følelsesmessige utfordringer, relasjoner, hverdagslige problemer, meningsfylte aktiviteter, eksistensielle problemstillinger og verdisyn.

Statistikk
Det primære måleinstrumentet var General Health Questionnaire-28 (GHQ-28). Sekundære utfallsmål var depresjon (Yale-Brown single item questionnaire), helserelatert livskvalitet (Stroke and Aphasia Quality of Life Scale (SAQQOL-39g)) og opplevelse av sammenheng (Sense of Coherence, SOC-13).

Faktorstrukturen av GHQ-28 ble evaluert ved eksplorerende faktor analyse (EFA) og en confirmatory (bekreftende) faktor analyse (CFA) ble anvendt for å vurdere faktorstrukturen funnet gjennom EFA opp mot originalstrukturen. Measurement invariance ble også vurdert.

For å evaluere effekten av intervensjonen, ble logistisk regresjon, generell lineær regresjon, independent sample t-tester (for uavhengige utvalg) og paired sample t-tester (for avhengige utvalg) benyttet for dataanalysene etter seks måneder. For analyse av 12 måneders dataene, ble i tillegg en lineær mixed model analyse brukt for å vurdere intervensjonens effekt på psykososial helse 12 måneder etter slaget, samt utforske om noen karakteristika fra baseline påvirket skåringen.

Resultater—Høyere nivå av opplevelse av sammenheng (SOC-13) hadde en beskyttende effekt på psykososial helse, men å adressere psykososiale utfordringer styrket ikke deltakernes opplevelse av sammenheng eller fremmet psykososial helse.

Del-studie I: Construct validity ble ikke bekreftet og sub-faktoranalyse basert på den opprinnelige faktorstrukturen av GHQ-28 bør derfor tolkes med forbehold. Faktorenes sammensetning antas å være påvirket av karakteristika i slag populasjonen. Det anbefales å utforske faktorsammensetningen i populasjonen hvor en eventuell sub-faktoranalyse er planlagt.

Del-studie 1I: Psykososial helse forbedret seg i løpet av de første seks månedene etter slaget både i intervensjons og kontroll gruppen, men det ble ikke funnet noen statistisk signifikant fordel av å delta i intervensjonen som supplement til vanlig oppfølging etter hjerneslag.

Del-studie III: Resultatene kunne ikke vise at deltakerne i intervensjonsgruppen opplevde bedre psykososial helse eller helserelatert livskvalitet og mindre depresjon og angst enn deltakerne i kontroll gruppen 12 måneder etter slaget. Deltakere som rapporterte omsorgsansvar, fatigue, depressive symptomer og komorbiditet, var mest utsatt for dårligere psykososial helse.

Konklusjon—Psykososial helse bedret seg gjennom det første året etter hjerneslaget. Størst bedring skjedde de første seks månedene etter slaget. I analysene ble det funnet undergrupper av deltakere som var mer sårbare for å oppleve psykososiale utfordringer, men en effekt av å delta i den samtalebaserte oppfølgingen i tillegg til vanlig slagbehandling ble ikke bekreftet statistisk.

På grunn av kompleksiteten av rammene for studien og utfordringer med validiteten til det primære utfallsmålet, er det vanskelig å trekke ut hvilke faktorer som er mest sentrale for at personer rammet av hjerneslag kan oppleve bedret psykososial helse ett år etter slaget. I denne avhandlingen, blir mulige årsaker og forklaringer for resultatene av studien diskutert.

Terms and abbreviations

C	Control
CFA	Confirmatory factor analysis
DIK	Dichotomous
EFA	Exploratory factor analysis
FQ-2	Fatigue Questionnaire-2
GDS	Guided self-determination
GHQ-28	General Health Questionnaire-28
I	Intervention
IP	Intervention personnel
KMO	Kaiser-Meyer-Olkin
LMM	Linear mixed model
MRC	The Medical Research Council in the United Kingdom
OT	Occupational therapist
PCA	Principal component analysis
RCT	Randomised controlled trial
RN	Registered nurse
SOC-13	Sense of Coherence-13
SAQOL-39g	Stroke and Aphasia Quality of Life scale-39g
SF-36	Short Form Questionnaire-36
T0	Time of inclusion and collection of clinical baseline data
T1	The one-month assessment time point—baseline
T2	The six-month assessment time point
T3	The 12-month assessment time point
Yale	The Yale–Brown single-item questionnaire

List of publications

I. Hjelle EG, Bragstad LK, Zucknick M, Kirkevold M, Thommessen B, Sveen U. The General Health Questionnaire-28 (GHQ-28) as an outcome measurement in a randomized controlled trial in a Norwegian stroke population. *BMC Psychol*. 2019 Mar 22;7(1):18. doi: 10.1186/s40359-019-0293-0

II. Hjelle EG, Bragstad LK, Kirkevold M, Zucknick M, Bronken BA, Martinsen R, Kvigne KJ, Kitzmüller G, Mangset M, Thommessen B, Sveen U. (2019). Effect of a dialogue-based intervention on psychosocial well-being 6 months after stroke in Norway: A randomized controlled trial. *J Rehabil Med.* 2019 Sep 3;51(8):557-565. doi: 10.2340/16501977-2585.

III. Bragstad LK, Hjelle EG, Zucknick M, Sveen U, Thommessen B, Bronken BA, Martinsen R, Kitzmüller G, Mangset M, Kvigne KJ, Hilari K, Lightbody CE, Kirkevold M, (2019). The 12-month effects of a dialogue-based intervention after stroke: A randomized controlled trial. Submitted to *Clinical Rehabilitation* Sept 24, 2019, In review.

1 Introduction

The three studies in this dissertation were conducted as part of the research project ‛Promoting psychosocial well-being following stroke’ (1) and build knowledge about the evaluation of a psychosocial intervention in a stroke population. Prior to this study, a dialogue-based intervention had been developed, tested and found feasible to carry out in a community setting, aiming at supporting the coping and life skills of stroke survivors to promote psychosocial well-being (2, 3).

The overall aim of this dissertation was to evaluate the effect of the psychosocial intervention on well-being after stroke in a multicentre randomised controlled trial (RCT). The studies focused specifically on the psychometric properties of the primary outcome measurement in addition to exploring the effect of the intervention. The first study assessed the reliability and validity of the General Health Questionnaire-28 (GHQ-28). In the second study, the effect of the intervention on psychosocial well-being at six months post-stroke was evaluated, and the third study evaluated the effect of the intervention at 12 months after the stroke onset.

1.1 Outline of the dissertation

The dissertation consists of seven chapters, including the reference list. Each sub-study is presented as published original papers (I–II) or in the submitted version (III) and is included at the end of the dissertation. This first chapter describes the background for addressing psychosocial challenges post-stroke, an introduction to the stroke condition and information on stroke rehabilitation in Norway. In addition, a description of the concept of ‛psychosocial well-being’, the results of previous studies on psychosocial interventions and the theoretical framework underpinning the development of the evaluated intervention are described. The rationale of this study is outlined in the last section of Chapter 1. Chapter 2 presents the aims and research questions of the three sub-studies. Chapter 3 describes the materials and methods used in this dissertation, and Chapter 4 presents the results of the three sub-studies. Chapter 5 discusses the results, followed by a methodological discussion. Chapter 6 presents the conclusion and clinical implications of this PhD study. Chapter 7 presents the references followed by the original papers and the appendices.

1.2 Background

Psychosocial challenges after stroke are common and include depression (4), anxiety (5) and general psychological distress and social isolation (6). Psychosocial problems affect long-term functioning, health-related quality of life (7-9) and motivation to participate in rehabilitation. A study has also found that psychosocial problems lead to a higher mortality rate (10). Previous studies have not provided clear recommendations on how to address these challenges in a way that is effective and feasible in a Norwegian community setting.

Several systematic reviews have investigated the effect of a psychosocial intervention on aspects of well-being such as mood or symptoms of psychological distress such as depression for stroke patients (4, 11-18). Some of these reviews address a specific type of intervention such as, for example, stroke liaisons (12), information provision (13), self-management programmes (14) or interventions to prevent particular challenges such as depression after stroke (10). Other reviews focus on the roles of specific professions targeting well-being in stroke rehabilitation (11, 15) or psychosocial interventions in general (17). In addition to the method of motivational interviewing (19), information provision (11, 13), liaison (12), social support (15) and help with self-management (14) have shown promising results on aspects of psychosocial well-being. However, statistically, the evidence is not strong, and more studies are warranted to inform the psychosocial follow-up for stroke patients living at home.

Research indicates that pharmacological treatment may be effective in treating post-stroke depression (9). A recently published systemic review concluded that the most effective antidepressants are selective serotonin reuptake inhibitors (17). However, systematic reviews reach different conclusions about the effect of pharmacological treatment for the prevention of depression. In Robinson et al.’s study (20), acute stroke patients were randomised to treatment with escitalopram over one year, problem-solving therapy or placebo. Robinson et al. found that the risk of developing post-stroke depression one year after stroke was four times higher for control group participants than for patients on escitalopram (20). In a Cochrane review, Hackett et al. found no benefit of pharmacological treatment for preventing depression (4, 10), while Salter et al. (21) concluded that antidepressant therapy in non-depressed stroke patients may reduce the odds of developing post-stroke depression. However, the frequency of depression has not changed significantly from the first Cochrane review of treatment for post-stroke depression in 2004 (22) to the update in 2014 (4), indicating that the phenomenon of psychological challenges is complex and stable and cannot be treated sufficiently by medications only.

1.3 Stroke

Stroke is a major cause of death and disability globally and imposes social and economic burdens on individuals, families and communities (23, 24). In Norway, the incidence of stroke is approximately 10,000 to 11,000 every year (25). According to a study on European stroke epidemiology and trends for the 21st century, stroke incidences are expected to increase in the coming years due to the increasing age of the population (26), but a decrease has been seen for the Norwegian population. According to a recent study on stroke incidence rates between 2010 and 2015 in Norway (27), the age-dependent incidence of ischaemic strokes is declining and compensates for the growth and ageing of the population. Improved primary and secondary prevention, including earlier detection and treatment of atrial fibrillation, are proposed as essential factors in the decline (27).

Approximately 85% of strokes are cerebral infarctions, and 10% to 15% are caused by an intracerebral haemorrhage (25). The consequences of a stroke depend on which part of the brain is injured and how this causes functional impairments. Some people recover completely from stroke, while others will have some degree of disability. Those who have had a mild stroke may only have limited problems such as temporary weakness of an arm or leg. People who have serious stroke may be permanently paralysed on one side of their bodies or lose their ability to speak (28). A major stroke can cause death.

The most common symptom of a stroke is sudden weakness or numbness of the face, arm or leg on one side of the body contralateral to the affected hemisphere. Other symptoms that may occur include difficulty speaking or understanding speech; difficulty seeing with one or both eyes; difficulty walking, dizziness, loss of balance or coordination; and confusion and severe headache with no known cause (29). Aphasia, which is an impairment of the ability to use language that often affects comprehension as well as expression (30), is a common feature due to brain damage from stroke. It is associated with worse outcomes both in the acute and chronic stages (31). Cognitive impairments are also common after a stroke, with executive and perceptual disorders being the most frequent (32). These might include problems with memory, attention, language, perception and organisation (33). Fatigue is a widespread challenge for stroke survivors. The prevalence varies significantly between studies from 25%

to 85% (34). A recent review of factors associated with fatigue identified demographics, emotional health, clinical factors, social factors and cognitive functions as potential associative factors for the experience of fatigue (35). Patients may experience a feeling of chaos and a lack of control after stroke. In addition, mood disturbance is common and might be presented as depression or anxiety. Approximately one-third of the patients (4, 36) report depressive symptoms, and 18% to 26% report anxiety (5, 37). Other common challenges are general psychological distress and social isolation (38). The transition from hospitals and rehabilitation units to the patient's own home after stroke is a critical phase for emerging psychosocial problems. Research has found that patients seem especially vulnerable to psychological stress during these periods of transition (39).

It is highly recommended that the acute medical treatment of the stroke patient take place in a stroke unit that specialises in treating the needs that arise after a stroke to facilitate the recommended treatment (40), decrease the death rate (41) and minimise the clinical outcomes (41-46). Stroke rehabilitation can take place at different levels of the Norwegian healthcare system.

1.4 Stroke rehabilitation in Norway

1.4.1 The context of stroke rehabilitation

Norway's more than five million inhabitants are spread over nearly four hundred thousand square kilometres, making it one of the most sparsely populated countries in Europe.
The organisational structure of the Norwegian healthcare system is built on the principle of equal access to services for all inhabitants, regardless of their social or economic status and geographical location. This overarching goal has been a longstanding feature of the Norwegian welfare system and has also been embedded in the national healthcare legislation and strategic documents (47). Healthcare is mainly organised at three levels: national/state (the Ministry of Health and Care Services), regionally through four hospital regions that oversee the provision of specialist services, and at the local level by 422 municipalities that are responsible for community care (48).

Healthcare reforms have seen shifts over the past decades. Since the beginning of the millennium, emphasis has been placed on structural changes in the delivery and organisation of healthcare and on policies intended to empower patients and users. Efforts have been made to improve coordination between healthcare providers, as well as to increase attention towards quality of care and patient safety issues (49). Several significant healthcare reforms have been implemented in Norway over the last decade. The Coordination Reform, which took effect in January 2012 (48), is of particular importance in the rehabilitation of stroke patients. The Coordination Reform focuses on prevention, integrating care in the community, strengthening healthcare in the municipalities and improving coordination between different levels of care and has the overriding aim of directing more investment towards primary care to curb the growth of expenditure in hospitals.

1.4.2 National Clinical Guideline for Treatment and Rehabilitation after Stroke

Rehabilitation after stroke is recommended (43, 50, 51) and might be provided as a prolonged part of the acute care treatment in institutions or in the patients' homes. The overall goal of stroke care and rehabilitation in Norway is to provide an effective and comprehensive treatment that addresses the patient's needs through different phases, from the onset of stroke symptoms through acute treatment, rehabilitation, new stroke prevention and further follow-up to a meaningful life. Rehabilitation after stroke usually takes place in a hospital or a rehabilitation unit during the first weeks. A prolonged course of recovery is often seen in which rehabilitation and care continue in outpatient clinics or the patient's home.

The National Clinical Guideline for Treatment and Rehabilitation after Stroke (43) has been developed to give recommendations for the content of acute care treatment and rehabilitation and to ensure evidence-based and equal treatment across the country. The guideline provides different recommendations that are adjusted to the diversity of needs in stroke rehabilitation. According to the guideline, patients with mild to moderate stroke may be discharged to their homes with follow-up by an interdisciplinary team. Discharging the subset of patients with mild to moderate stroke severity with follow-up in the community is recommended in a consensus document on early supported discharge (52). Patients with severe stroke should be treated in specialised rehabilitation units.

Typically, the follow-up after stroke consists of services from different healthcare personnel such as physicians, nurses, occupational therapists, physical therapists or other specialties like speech therapists. In the later stages of stroke rehabilitation, it is recommended that the specialised healthcare services provide an evaluation of function and severity, re-evaluation of goals, and guidance to the stroke patient and his or her relatives and, if needed, to the healthcare personnel involved in the patient's rehabilitation in the municipality.

The action plan for stroke in Europe 2018–2030 (53) notes that life after stroke merits recognition. With an increasingly ageing population and more people surviving stroke, stroke survivors and their families need to feel empowered to optimise quality of life and independence (53). The healthcare services in Norway still struggle to ensure geographical and social equity in access to healthcare (49). Research shows that there is a tendency to focus on treating physical symptoms in stroke rehabilitation in the community (54), and systematic psychosocial rehabilitation is rarely included. Since there is not necessarily a direct relationship between improved physical functioning and improved psychosocial well-being (16, 55, 56), only focusing on improving physical functioning is not sufficient to achieve psychosocial well-being.

1.5 Psychosocial well-being

1.5.1 Defining psychosocial well-being

There is no single definition of subjective well-being, but there is general agreement that at a minimum, it includes a greater prevalence of positive than negative emotions and moods, satisfaction with life, a sense of fulfilment and positive relationships (57-60). Subjective well-being commonly implies being in good health and experiencing well-being and life satisfaction, but studies indicate that it is dependent upon finding a balance between body, mind and spirit in the self and on establishing and maintaining a harmonious set of relationships within the person’s social context and external environment (58). Subjective well-being goes beyond the activities of daily living and disease because it directs attention to the person as a complete social, psychological and spiritual being (58).

In the development and feasibility stage prior to this study, Næss’ definition of ‘psychological well-being’, consisting of four elements, was used to understand the concept (2, 3, 58). Næss defines psychological well-being as 1: a basic mood of contentment and absence of pervasive feelings of sadness or emptiness; 2: participation and engagement in meaningful activities; 3: good social and mutual relationships; and 4: a self-concept characterised by self-esteem, usefulness and belief in one’s own abilities (3, 58). To emphasise the importance of social relations, the word ‘social’ was added in the early stages of the development of the overall study (2) and is also applied in the studies that comprise this dissertation.

1.5.2 Psychosocial interventions

Psychosocial interventions are characterised by the targeting of psychological or social factors that contribute to well-being and help people cope with life stressors (55, 57, 59, 60). Scientific databases were searched for studies of psychosocial interventions. The studies of interest target patients with a clinical diagnosis of ischaemic or haemorrhagic stroke and applied a psychosocial intervention to promote well-being. In principle, it can be argued that all interventions that target an aspect of psychosocial well-being can be labelled psychosocial interventions. To enable the comparison of previous research to the results of the current study, the search was limited to randomised controlled trials or systematic reviews that included a type of psychosocial intervention provided by healthcare personnel. In addition, only studies that conducted the intervention after discharge from a hospital or rehabilitation centre were included to enable the comparison of the results to our community-based intervention.

The examined systematic reviews (4, 11-18) emphasised different aspects that may be important for a successful intervention. According to Cheng et al., motivational interviewing was associated with an improvement in mood (18). Hackett et al. (10) and de Man-van Ginkel et al. (11) supported this finding. Regarding information provision, the reviews draw different conclusions. For example, de Man-van Ginkel et al. reported strong evidence of the benefit of information programmes for preventing post-stroke depression, while others evaluating the same type of intervention reported only a small or weakly positive (6, 13) clinically relevant difference. Fryer et al. investigated different types of self-management programmes (14) and found some trends supporting the use of these programmes to improve mood and independence in activities, but these trends were not significant. Stroke liaison workers may benefit patients with mild to moderate disability, according to Ellis et al. (12). Salter et al. evaluated social support interventions, including care coordination, and found little evidence to support their effectiveness (15). Whyte et al. (16) found that psychotherapeutic intervention may be useful in preventing depression, but they called for more research. Starkstein and Hayhow concluded that even though psychosocial interventions are potentially useful treatments, they remain substandard in quality and are in need of replication (17).

Further investigation of relevant individual studies was conducted to learn more about the key elements applicable to clinical practice. In addition to the systematic reviews, 14 randomised controlled trials were examined (19, 20, 61-72). The studies, which were conducted from

1997 to 2019, represent a wide variety of psychosocial approaches aiming to promote well-being or prevent depression following stroke. Key elements, timing and duration of the intervention, target group and outcome measurements were particularly investigated.

Key elements of interventions

It is important to identify key features of the programmes (73), but this was challenging because of the wide variety of interventions that are labelled ʽpsychosocial.ʼ Six different interventions were described in the primary studies. Stroke care coordination programmes were commonly applied (23, 63-66, 69, 71). The content varied across the studies, but they all provided some type of information, support and liaison to services. Another intervention was a psychoeducational programme (70) based on a conceptual model that hypothesises that when a major stressor such as a stroke occurs, outcomes (perceived health) may be buffered by interventions that seek to change the perception of the situation and increase the use of social resources and coping strategies. A lifestyle redesign programme was applied in one study (74) of the occupational science theory. It emphasises the therapeutic role of lifestyle redesign in enabling participants to actively and strategically select an individualised pattern of personally satisfying and health-promoting occupations (67, 75).

The three studies with results that supported the evaluated intervention focused on different characteristics that contributed to the result. Using sessions of motivational interviewing, Watkins et al. affected mood status three (19) and 12 months (76) post-stroke, measured by the GHQ-28. Motivational interviewing is a collaborative, goal-oriented style of communication that works with patients’ dilemmas and ambivalence, supporting and reinforcing optimism and self-efficacy. The method aims to help patients recognise and realise their own solutions to problems by adjusting to different aspects of living with stroke (19). Timing, intensity and therapist training were identified as possible factors contributing to their outcome.

Graven et al.’s (66) community-based rehabilitation programme proved effective in reducing post-stroke depressive symptoms by using an integrated approach to the pursuit of patient-identified activities. Graven et al.’s (65) intervention had several elements of coordination, such as telephone contacts, information, home visits and referral to relevant health services. In addition, they added collaborative goal-setting to the intervention. The collaborative, individualised goal-setting, the liaisons to appropriate services and the promotion of physical exercise and activity were noted as important elements to prevent depression as measured by the Geriatric Depression Scale (GDS).

Hill et al.'s study (76) aimed to improve the patient's problem-solving skills so that the patient felt that he or she could take control of coping. Their primary hypothesis was that problem-solving therapy would reduce mood disorders as measured by the GHQ-28, reduce rates of depression and lead to better social function and satisfaction with care. The group-based problem-solving therapy in itself is emphasised as important in this result.

Timing, dose and frequency

Issues regarding the timing of interventions aiming to promote psychosocial well-being or prevent psychological problems after stroke are mentioned in the systematic reviews. First, it is unclear when and for how long the intervention should be given, but there may be a time window, although not specified, in which the benefit is favourable (16). Fryer el al. (14) identified questions about the ideal frequency, duration and mode of sessions as potential challenges for future researchers. Challenges in finding the optimal time to apply the intervention and to whom were also found in de Man-van Ginkel et al.'s (11) review. The duration, dose and frequency of the interventions varied across the studies, and the initiation of the intervention was different. The shortest intervention lasted four weeks (19), and the longest lasted up to nine months (61, 65-67). The number of contacts/sessions varied from zero (19) to no limit (65). The dose of interventions categorised as stroke care coordination ranged from 0–50 contacts. This variation can be explained by the individualised nature of this type of intervention. The studies were conducted in six countries on three continents. Because the length of the hospital and rehabilitation stay varies across countries and depends on the in-hospital rehabilitation services that each hospital delivers, it was challenging to compare the studies based on a timeline.

Target group

Determining if there are specific sub-groups of participants that particularly benefit from the intervention is important. Ellis et al. (12) found little evidence to support stroke liaison to all groups of patients, but stated that there appeared to be significant benefits to stroke liaison input for patients with mild and moderate disability. Other studies such as Ertel et al.'s (77) examine the possibility that their evaluated psychosocial intervention might not suit all participants. Their analyses suggest that the intervention may have boosted recovery among patients who were well enough to participate fully in the intervention, but they also found that the psychosocial interventions were harmful for frail sub-groups. Possible reasons were timing compared to need and limitations in health and environment that prevented them from fully participating (77).

However, all the investigated primary studies had similar inclusion and exclusion criteria, which resulted in a homogenous sample from the stroke population from which those with the most severe disabilities or cognitive challenges were excluded. This means that in all the evaluated studies, the interventions were mainly evaluated for patients with mild to moderate stroke impairments.

Outcome measures applied

It is essential to find the most suitable outcome measures and to be aware of different options that might be useful for capturing the effect of a psychosocial intervention (4), but the number of options for different outcome measurements can be overwhelming. Twenty-four different measurements were applied in the investigated studies, and the choice of outcome measurement depended on what aspects of psychosocial well-being the study targeted.

Some studies assessed symptoms of anxiety or depression, while others assessed quality of life, mood, well-being, participation, emotional health, stress, stroke impact, coping, problem-solving skills or satisfaction with services. The most commonly applied measurement was the Hospital Anxiety and Depression Scale (HADS). Six studies used the HADS as an outcome measure for anxiety and depression (62, 64, 67, 69, 71) or mood (61). Other commonly applied outcome measures were different versions of the General Health Questionnaire (GHQ) evaluating mood (19, 64-66, 76). Three studies used the Short Form Health Survey-36 (SF-36) to evaluate quality of life (62, 78) or well-being and participation (67). Other outcome measurements used were the Patient Health Questionnaire-9 (PHQ-9), the General Anxiety Disorder-7, the EQ-5D-5L, the Adult Hope Scale and Warwick and Edinburgh Mental Well-Being Scale (68). The outcome measurement was not only connected to evaluations targeting different aspects of psychosocial well-being. Studies also used different outcomes to target the same aspect of psychosocial well-being. For example, for depression, the HADS (71), Yale (19), Beck Depression Scale (63) and DSM-IV (20) were applied.

1.6 Theoretical and conceptual framework applied in the development of the intervention

Sense of coherence, narrative philosophy and guided self-determination are the theoretical frames of reference that guided the development of the intervention and were assumed to be potential explanatory factors of a relationship between stroke, psychosocial intervention and well-being after stroke. The theoretical framework has been thoroughly outlined in previous dissertations based on the development and feasibility of the intervention (79, 80), but will be outlined briefly in the next chapter.

1.6.1 Sense of coherence

The experience of coping with stressful situations is a key factor in the experience of psychosocial well-being (81). Antonovsky's theory connects health and well-being to the experience of a sense of coherence in life and claims that the way people view their lives has a positive influence on their health (81). A high sense of coherence is associated with experiencing life events as comprehensible, manageable and meaningful (81-83). Antonovsky argues that individuals with a strong sense of coherence will make sense of their world as rational, understandable, structured and predictable (comprehensible). They will perceive that they have access to sufficient resources to help them cope adequately with the problems they confront (manageability). Finally, they will have the capacity to find meaning, values and motivation to persist in disruptive conditions such as illness or disability (meaningfulness).

According to Antonovsky, a salutogenetic orientation applied in studies directs the researcher to explain how people manage well despite adverse health experiences. Antonovsky pointed out that there are differences in the amount of personal resources available for individuals to meet the demands posed by stressful events and that a higher sense of coherence might have a protective effect on the adverse health experiences and potentially stressful situations a stroke might impose. This has been supported by Eriksson and Lindstrom (83), who found that a sense of coherence seems to be a health-promoting resource that strengthens resilience and develops a positive subjective state of health. They concluded that promoting a sense of coherence is valuable for health promotion and recommend that it be implemented.

Based on the development and modelling of the intervention in this study, it was assumed that the sense of coherence could be strengthened when events and life situations were perceived as understandable, manageable and meaningful (2). This made a sense of coherence an essential intermediate goal for promoting psychosocial well-being and an important outcome measure (1) of the intervention in this study.

1.6.2 Use of narratives

A narrative is consistent with the terms ʽstory', ʽtale' or ʽhistory' (84). This approach was based on previous research and suggested that telling one's story promotes well-being (85, 86). The primary focus of a narrative approach is people's expression of their experiences of events in life. This storytelling can help create meaning in a new or changed existence and connect the present to the past and future. In this way, narratives provide coherence across the life span as individuals reflexively link various life experiences under one umbrella of meaning (84). Thus, storytelling might contribute to repairing the damage caused by illness.

The effectiveness of a narrative practice on the psychological needs of chronically ill patients has been previously documented (87, 88), and the use of narratives has proven effective on factors such as hope, positive emotions and depression in individuals diagnosed with depression (89). Research suggests that telling one's story is a fundamental need after a traumatic event and that co-constructing stories is assumed to promote psychosocial well-being after stroke (90, 91). Storytelling may contribute to subjective well-being by stimulating reflection, adjustment and, by strengthening identity, self-understanding and self-esteem (86).

Narrative therapy has been offered as a viable treatment in handling the psychosocial and spiritual needs of stroke survivors (91). The therapist helps a patient deconstruct his or her problem-saturated story, co-construct inner strengths and beliefs and reconstruct meaning and purpose in life. According to Chow, instead of focusing on disabilities and limitations, narrative therapy reconnects the survivors' inner resources, skills, competencies and abilities (91). A theoretical and practical framework has been published for use in narrative therapy as part of stroke rehabilitation in group practice (91), but the effect of narrative therapy as part of individual rehabilitation after stroke is less known.

1.6.3 Guided self-determination

The guided self-determination (GSD) approach was developed by Vibeke Zoffmann (92) for use in the field of difficult diabetes care and has been proven effective on distress and the development of new life skills for persons with diabetes (93-95). GDS was originally tested as a problem-solving process for patients with diabetes (95), but was later applied to other groups, such as patients with schizophrenia (96).

The method was founded on empowerment philosophy and highlights the importance of being in control of one's own recovery and adjustment process. The role of the healthcare professional is conceptualised as a ʿsupporterʾ or ʿcoachʾ rather than a ʿcarerʾ or ʿtherapistʾ (97). The intervention was designed to empower the participants to make decisions about their well-being based on their values and perspectives (92). A central feature and strength of the method is its structure. The method includes reflection sheets that form the basis for each dialogue and work as a guide for the patient and professional. The structure keeps the conversation focused and clarifies how the patient can tackle specific challenges.

Worksheets adjusted to the needs of the stroke patient were created during the modelling phase prior to the feasibility study (2, 3). The themes were chosen based on the assumed psychosocial needs identified in the feasibility work and included mood, social relationships, body sensation, daily activities and identity. The worksheets had simple text, short sentences, large fonts, bolded keywords and illustrations, and they used colours to enhance the interpretation of participants with aphasia or cognitive impairments (79). The worksheets are shown in Table 4 in the Methods section. A model (Figure 1) (3) was applied in the development stage of the intervention to visualise its theoretical assumptions.

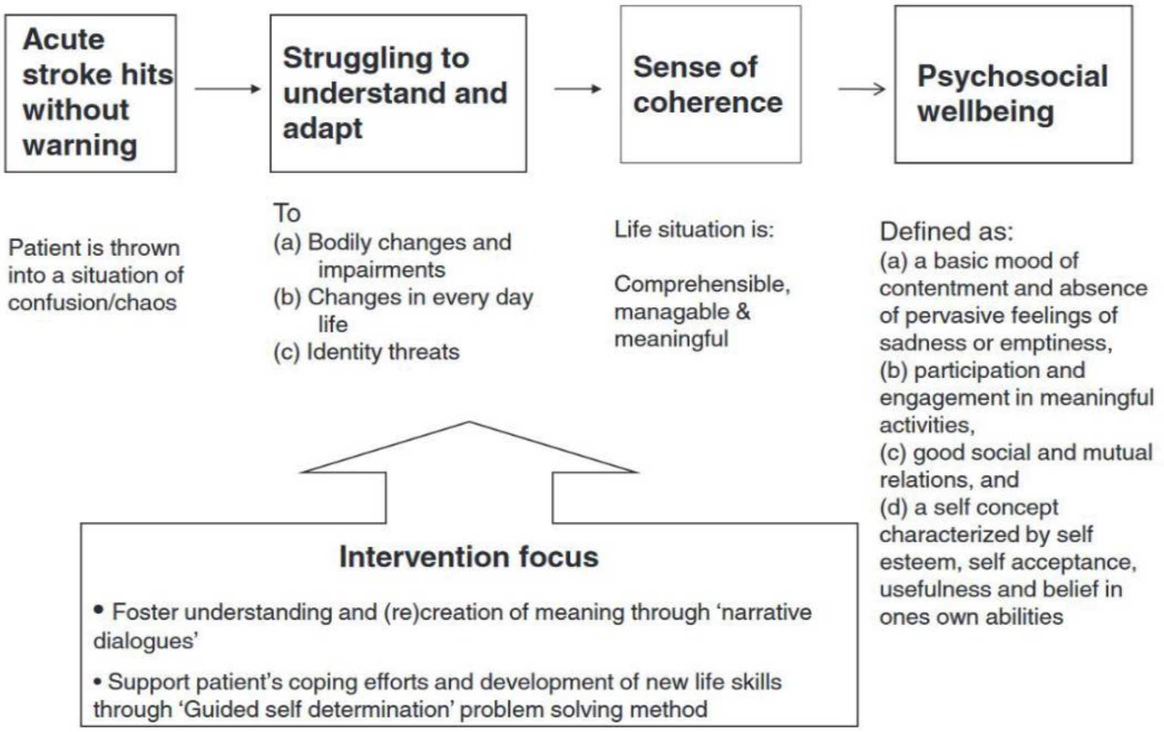


Figure 1 The theoretical assumptions of the intervention

1.7 Rationale for the randomised controlled trial

There is increasing awareness of the psychosocial challenges and emotional symptoms that may be prevalent after stroke and that impact the lives of stroke survivors. Based on previous research that developed and evaluated interventions addressing these challenges, some specific factors seem important in promoting psychosocial well-being after stroke. In addition to motivational interviewing (19) and problem-solving therapy (76), having a goal-oriented approach (65), information provision (11, 13), liaison (12), social support (15) and help with self-management (14) seem to be essential. The inconsistency regarding key elements in the previous interventions challenges the translation of knowledge to practice. The studies that demonstrated a significant effect on aspects of psychosocial well-being (19, 65, 76) applied various interventions, outcome measures, timing and intensity; the analyses varied, highlighting different aspects that may be important for a successful intervention.

Several studies have been conducted with inconclusive or little evidence of their effectiveness. This does not necessarily establish that psychosocial interventions after stroke are ineffective, but that the trials failed to provide evidence of their effectiveness. As Redfern et al. (98) pointed out in their review of complex interventions in stroke care, commonly, interventions had not been adequately developed or evaluated, which explains the failures to demonstrate efficacy. They encouraged greater attention to theoretical development and methodological quality.

The intervention in our study underwent extensive groundwork with explorations of patients' needs, synthesised previous knowledge on psychosocial intervention and developed a theoretical foundation to provide accounts of the mechanisms that are assumed to contribute to psychosocial well-being. Based on the development and feasibility studies (2, 3), the intervention in our study was targeted to strengthen each participant's coping process by enhancing the degree of understanding, manageability and meaning (sense of coherence) in his or her life after the stroke. We hypothesised that dialogue-based sessions inspired by guided self-determination in the early adjustment phase following a stroke could lead participants to a higher level of sense of coherence, psychosocial well-being and health-related quality of life and less depression and anxiety (1).

2 Aims of this dissertation

The overall aim of this dissertation was to evaluate the effect of a previously developed and feasibility-tested, dialogue-based psychosocial intervention on well-being after stroke in a multicentre randomised controlled trial (RCT). Table 1 presents the titles, aims and research questions of the three sub-studies.

Table 1 Overview of the three sub-studies of the dissertation

	Sub-study I	**Sub-study II**	**Sub-study III**
Title	The General Health Questionnaire-28 (GHQ-28) as an outcome measurement in a randomized trial in a Norwegian stroke population – evaluating psychometric properties	Effect of a dialogue-based intervention on psychosocial well-being six months after stroke in Norway: A randomized controlled trial	The 12-month effects of a dialogue-based intervention after stroke: A randomized controlled trial
Aim	To explore the psychometric properties of the GHQ-28 when applied in a Norwegian stroke population by evaluating the internal consistency, factor validity and measurement invariance	To evaluate the effect of a dialogue-based intervention in addition to the usual care on psychosocial well-being six months after stroke	To evaluate the effect of a dialogue-based intervention in addition to usual care on psychosocial well-being 12 months after stroke
Research questions	Is the factor structure of the GHQ-28 in this study comparable to the original? Are the responses at baseline and the six-month time-point comparable?	Will participants in the intervention group experience significantly higher levels of psychosocial well-being, health-related quality of life and lower levels of depressive symptoms and anxiety than participants in the control group six months post-stroke?	Will participants in the intervention group experience significantly higher levels of psychosocial well-being, health-related quality of life and lower levels of depressive symptoms and anxiety than participants in the control group one year post-stroke?

3 Materials and methods

Some research designs are more powerful than others in their ability to answer research questions about the effectiveness of interventions. In this hierarchy of evidence, the randomised controlled trial is considered the gold standard (99). The different stages the Medical Research Council in the United Kingdom (MRC) suggested in evaluating a complex intervention (100) have guided the overall project, and the CONSORT guideline for reporting a randomised controlled trial has been followed (99).

3.1 Evaluating complex interventions

Complex interventions are characterised by their simultaneous inclusion of several interacting components that may, in addition, interact with the context during the intervention delivery (101, 102). Stroke rehabilitation is a complex process at multiple levels that may require medical, psychological, social, physiological and environmental interventions (98). The MRC has developed a framework to guide the evaluation of complex interventions (100, 103). A revision of the guidance, reflections and comments on the guideline was later published (98, 103). The framework describes recommendations regarding the development and testing of complex health interventions and consists of four interacting phases. The first is the initial development phase, the second is the modelling and exploratory trial phase, the third is the evaluation phase, preferably conducting an RCT, and the final phase is the long-term implementation (Figure 2) (101).

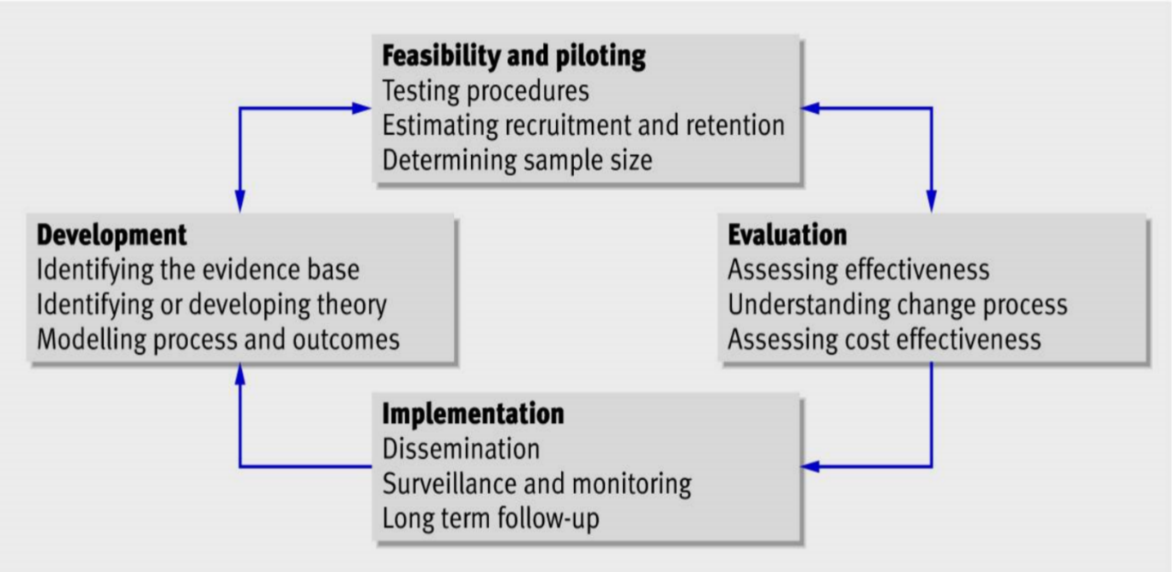
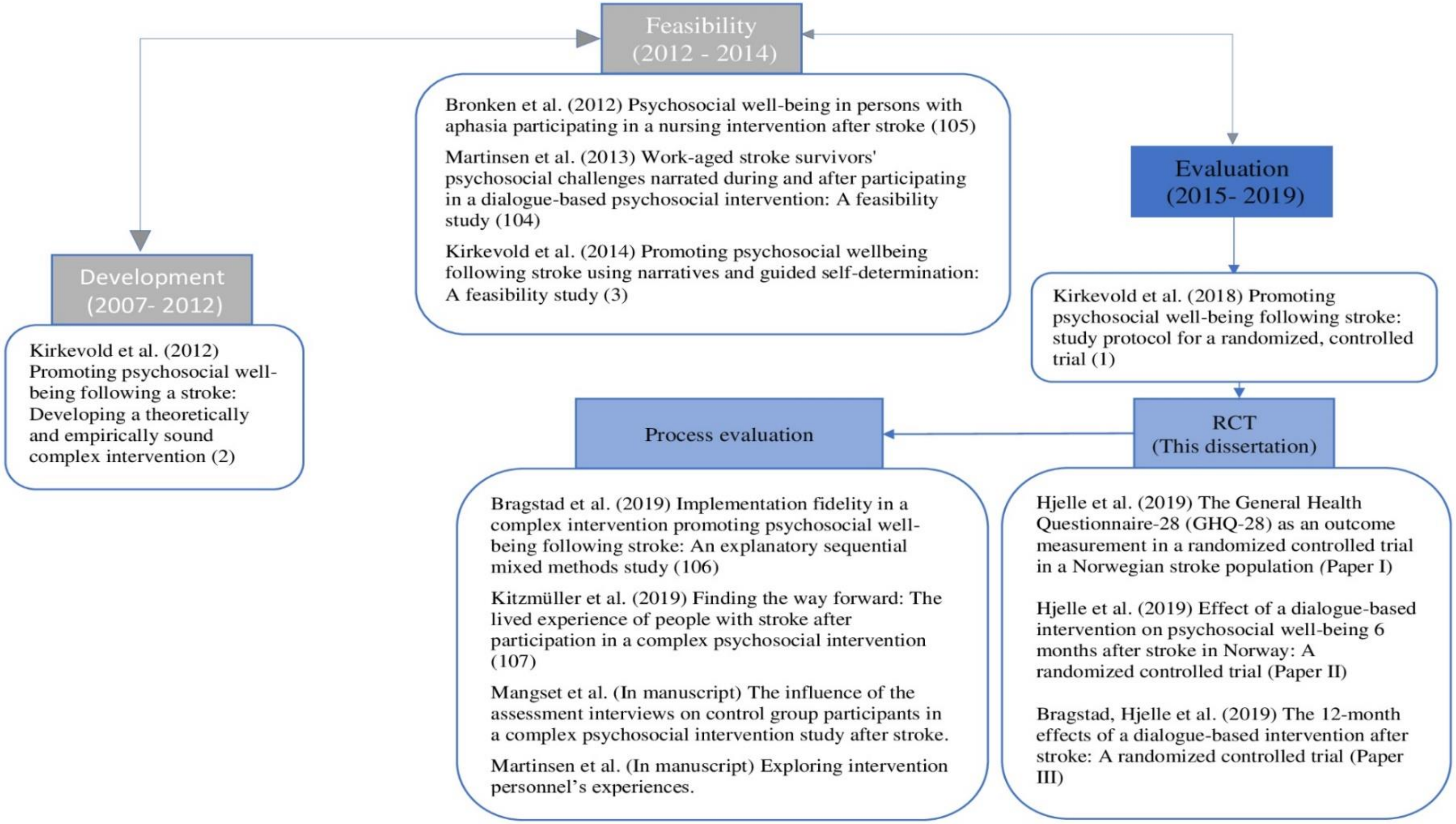


Figure 2 The framework of developing and evaluating complex interventions

Several studies were conducted prior to and in parallel with the studies included in this dissertation, as is recommended when one is evaluating a complex intervention (103) (see Figure 3). The first stage, development, includes identifying the existing evidence, identifying and developing theory and modelling the process and outcomes. This was conducted and reported (2) prior to the second stage, which involved piloting or feasibility evaluation. Feasibility studies of the intervention (3, 104, 105), in which the intervention was tailored to fit persons with stroke, were conducted prior to the evaluation phase. Because process evaluations are recommended, the intervention fidelity was evaluated (106), and qualitative interviews of participants in the intervention (107) and control group, in addition to the intervention personnel, were conducted after the participants had finished all assessments in the RCT. The papers reporting the control group participants' experiences and the intervention personnel's experiences are still in manuscript. Figure 3 illustrates the process of studies and publications through the development and feasibility phases and the parallel studies to the current three in this dissertation.



Kirkevold et al. (2012) Promoting psychosocial well-being following a stroke: Developing a theoretically and empirically sound complex intervention (2)

Bronken et al. (2012) Psychosocial well-being in persons with aphasia participating in a nursing intervention after stroke (105)

Martinsen et al. (2013) Work-aged stroke survivors' psychosocial challenges narrated during and after participating in a dialogue-based psychosocial intervention: A feasibility study (104)

Kirkevold et al. (2014) Promoting psychosocial wellbeing following stroke using narratives and guided self-determination: A feasibility study (3)

Kirkevold et al. (2018) Promoting psychosocial well-being following stroke: study protocol for a randomized, controlled trial (1)

Bragstad et al. (2019) Implementation fidelity in a complex intervention promoting psychosocial well-being following stroke: An explanatory sequential mixed methods study (106)

Kitzmüller et al. (2019) Finding the way forward: The lived experience of people with stroke after participation in a complex psychosocial intervention (107)

Mangset et al. (In manuscript) The influence of the assessment interviews on control group participants in a complex psychosocial intervention study after stroke.

Martinsen et al. (In manuscript) Exploring intervention personnel's experiences.

Hjelle et al. (2019) The General Health Questionnaire-28 (GHQ-28) as an outcome measurement in a randomized controlled trial in a Norwegian stroke population (Paper I)

Hjelle et al. (2019) Effect of a dialogue-based intervention on psychosocial well-being 6 months after stroke in Norway: A randomized controlled trial (Paper II)

Bragstad, Hjelle et al. (2019) The 12-month effects of a dialogue-based intervention after stroke: A randomized controlled trial (Paper III)

Figure 3 The process of studies through the development and feasibility phases and the parallel studies to the current three in this dissertation

3.2 Trial design

3.2.1 Study design

This study was a prospective multicentre longitudinal RCT. The participants were included from several geographical areas and 11 different centres. The participants were followed for one year post-stroke with assessments at one (T1), six (T2) and 12 (T3) months (Figure 4).

3.2.2 Sample size

The sample size was based on the primary outcome measurement, GHQ-28. With 80% power and a significance level α at 0.05, the number of participants necessary was estimated at 300 (150 in each arm of the trial). To allow for 10% dropout, the goal was to recruit a minimum of 330 patients. Following Watkins et al.'s results, we deemed an odds ratio of 1.6 or higher between groups with normal mood after six and 12 months to be clinically relevant (19). This required analysing the data in a repeated-measurement mixed-models analysis with two correlated measurements for each patient (i.e. one at six months and one at 12 months). For the logistic regression analysis of the dichotomised GHQ-28 at six months, the power of finding a statistically significant difference between groups was 80% for an OR of 1.9 or higher.

3.2.3 Randomisation and blinding

The randomisation was done in accordance with a computer-generated randomisation list. The procedure was created by a statistician who was independent of the research group. To minimise allocation bias and ensure an equal group size in the intervention and control groups, the participants were randomised in blocks of 10 that were stratified by study centre. Opaque randomisation envelopes with a five-digit patient identification number printed on the outside and a note specifying intervention or control inside were prepared by an assistant who was independent of the research group. Two regional study coordinators carried out the randomisation process following the baseline assessment. The assessors at T2 and T3 were blinded to the group allocation.

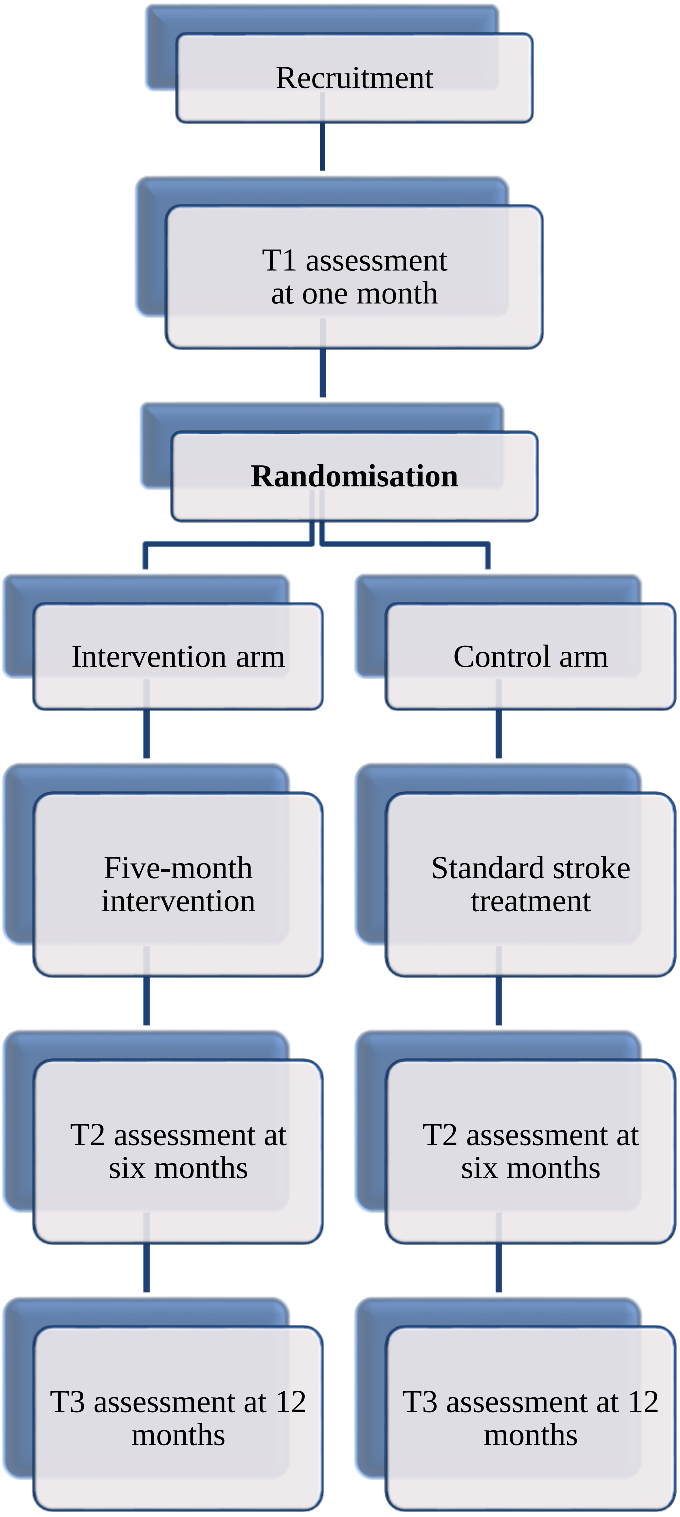


Figure 4 Trial design

3.2.4 Enrolment

Enrolment started in November 2014, and the last participant was recruited in December 2016. Participants were recruited from acute stroke or rehabilitation units in eastern Norway. Participants were identified by specifically trained staff in the participating units based on inclusion and exclusion criteria (Table 2). They were given oral and written information about the study.

Table 2 Inclusion and exclusion criteria

Inclusion	Exclusion
Adults over 18 years of age Suffered an acute stroke within the last month Medically stable Sufficient cognitive functioning to participate Able to understand and speak Norwegian Able to give informed consent	Moderate to severe dementia Serious somatic or psychiatric disease Severe aphasia

The stroke aetiology, side localisation of the stroke symptoms, cognitive function and language difficulties were recorded at baseline after obtaining informed consent. Neurological deficits were evaluated using the National Institutes of Health Stroke Scale (NIHSS) upon admittance to the hospital (108). Information regarding cognitive function (Mini Mental Status Evaluation (MMSE)) was collected from the participant's medical record. If an MMSE was not available, the recruiting personnel evaluated whether the participant had sufficient cognitive functioning to participate based on other information in the medical record, their own expertise or discussion with the interdisciplinary team.

3.2.5 Participants

Six hundred and seventy stroke patients were assessed for eligibility, of whom 353 consented to participate. Three hundred and twenty-two participants were randomly assigned to the intervention (n = 166) or control (n = 156) group. Between consent and the baseline assessment, 19 participants were excluded, and 12 chose to withdraw from the study. Reasons for withdrawal are listed in the flow chart (Figure 5). Twenty-three participants (7.1%) in the intervention group and 14 (4.4%) in the control group were lost to follow-up at six months. Consequently, 285 participants (88.5%) completed the follow-up assessments at T2. At T3, 282 (87.6%) completed the assessments.

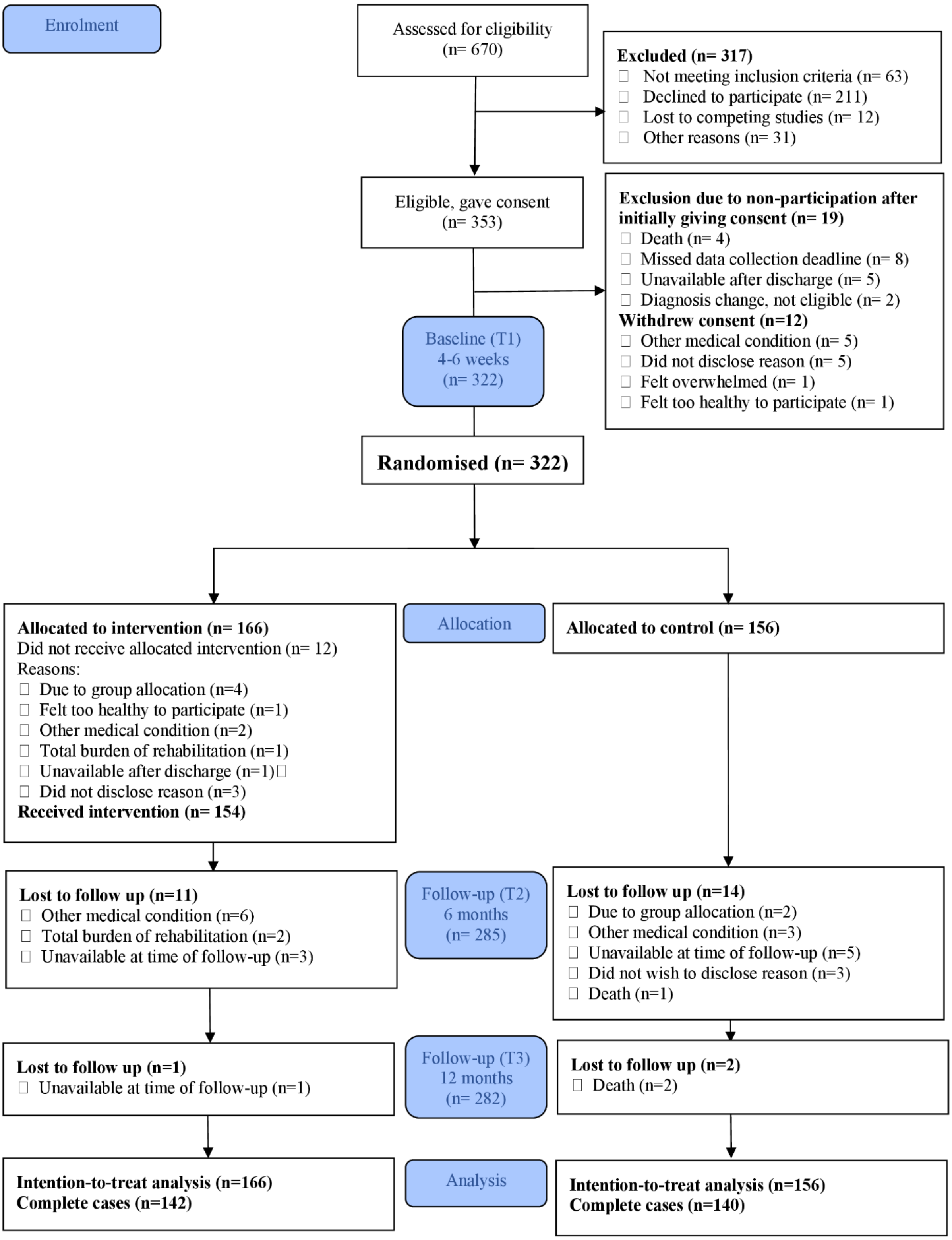


Figure 5 Flow chart

3.3 Characteristics of the participants

Table 3 shows the characteristics of the participants. Their ages ranged from 20 to 90 years, with a mean age of 66.2 years (SD 12.6). There were 190 males (59%) and 132 females (41%) recruited into the study. According to the measurement of neurological deficits, the NIHSS, the majority of the participants (70%) had minor symptoms (scored between 0 and 5 on the NIHSS). According to the national register for stroke patients admitted to hospital in Norway in 2015, our participants were on average eight years younger than the national stroke population. We included 5% more men than expected based on the stroke population in Norway and fewer patients with high stroke severity (25).

Detailed information on the reasons for non-participation was limited due to strict ethical guidelines limiting questions regarding why patients chose to decline. However, the two most common reasons cited were that they felt the intervention did not suit them or that they had too much going on to commit to participating. The Regional Committees for Medical and Health Research Ethics (REC) gave permission to register information on the sex and age of the participants who declined. Unfortunately, not all recruiting centres provided complete data. However, in the largest recruiting centre (n = 126), the mean age of those who consented was 64.1 years compared to 64.4 years in the group that did not consent (p = 0.893). The proportion of men and women who consented—60.8% and 39.2% respectively, compared to 58.2% and 41.8% who did not consent (p = 0.679)—showed no sex disproportion between the groups.

Table 3 Sample characteristics (n = 322) at baseline

Variable	**Intervention group (n=166)**	**Control group (n=156)**
Demographics and psychosocial factors		
Age, years *mean* (SD)	66 (12.1)	65 (13.3)
Female gender	67 (40.4)	65 (41.7)
Living with someone	117 (70.5)	101 (63.7)
Education ≥ college/university degree (n = 165; 155)	51 (30.8)	52 (33.3)
Working prior to stroke (n = 165; 156)	64 (38.6)	57 (36.5)
Receiving rehabilitation services	114 (68.7)	99 (63.5)
No caring responsibility	129 (77.7)	120 (76.9)
Having social support	154 (98.8)	152 (97.4)
Clinical characteristics		
Stroke aetiology (n = 147; 144)		
Ischaemic infarct	128 (87.1)	136 (94.4)
Haemorrhage	19 (12.9)	8 (5.6)
Stroke symptom localisation (n = 164; 151)		
Right hemisphere	65 (45.8)	56 (41.2)
Left hemisphere	70 (49.3)	74 (54.4)
Bilateral	7 (4.9)	6 (4.4)
NIHSS, *median* (IQR) (n = 126; 114)	4.0 (1.0–7.0)	2.5 (1.0–6.0)
0–5	85 (67.5)	85 (74.6)
6–10	28 (22.2)	17 (14.9)
11+	13 (10.3)	12 (10.5)
No comorbidity	31 (18.7)	32 (20.5)
UAS, *median* (IQR) (n = 163; 156)	52 (50–52)	52 (50–52)
MMSE, *median* (IQR) (n = 63; 65)	27 (25–29)	28 (26–30)
Outcome measurements		
Normal mood (GHQ-28<5) (n = 160; 151)	50 (30.0)	46 (29.0)
Stroke and Aphasia Quality of Life scale (SAQOL-39g) (n = 154; 143) (Scale 1–5), *median* (IQR)	4.35 (3.7–4.5)	4.25 (3.7–4.6)
Physical domain	4.62 (4.0–4.9)	4.53 (3.9–4.8)
Communication domain	5.00 (4.8–5.0)	5.00 (4.8–5.0)
Psychosocial domain	3.93 (3.3–4.5)	3.84 (3.2–4.3)
Feeling sad or depressed (Yale)	29 (17.5)	43 (27.6)
Sense of coherence (SOC-13) (Scale: 13–65), *mean* (SD) (n = 165; 156)	50.6 (5.4)	50.4 (5.8)
Feeling fatigued (FQ-2), *mean* (SD) (n = 165; 156)	88 (53.3)	87 (55.8)
Lee's fatigue scale (Lee 5): (Scale: 1–10) *mean* (SD) (n = 164; 156)	3.47 (1.8)	3.58 (1.9)

Values are reported as the n (%) unless stated otherwise. SD indicates standard deviation, IQR indicates interquartile range, NIHSS indicates National Institutes of Health Stroke Scale, MMSE indicates the Mini Mental Status Examination and UAS indicates Ullevaal Aphasia Screening.

3.4 The intervention

The intervention consisted of eight individual sessions between a registered nurse (RN) or an occupational therapist (OT) and the participant. The sessions addressed feelings, thoughts and reflections related to the patient's experiences after stroke and were based on findings in the development and feasibility studies (2, 3) that found that being supported through a difficult time enabled patients to tell and (re)create their stories, underscoring the patients' being supported in their attempts to cope with the situation.

The study was primarily conducted in a community care setting in Norway, and the intervention was mainly delivered in the participants' homes. All participants received standard stroke treatment as part of usual care that included acute treatment in stroke units and rehabilitation centres and/or in the community. As recommended in the Norwegian National Clinical Guideline for Treatment and Rehabilitation after Stroke (43), the participants had follow-up by their general practitioner after discharge and through multidisciplinary teams based on needs and the availability of the services in each municipality. Section 1.4 describes the typical content of the rehabilitation services.

The first of eight sessions ideally started four to eight weeks after stroke onset. The number of sessions was chosen to balance the ideal with the realistic (i.e. as few encounters as possible but enough to provide adequate support). The interval between the meetings was one, two or three weeks, with more frequent intervals in the beginning. Since the intervention aimed at promoting psychosocial well-being, it was essential to start the intervention as early post-stroke as possible after the baseline assessment. Therefore, the interventions could partly or entirely take place in a rehabilitation unit or another place where the participants were at the time of the intervention. According to the timeline in the intervention protocol (1), all eight meetings should be conducted within four to five months.

Participants were given worksheets about different topics for each session as part of the intervention (Table 4 describes the topics). The participants were in charge of the dialogues in the sense that they decided what to focus on in each encounter and the healthcare professionals followed the participants' lead. If the participant introduced a topic that was different from the topic suggested for the particular session, the healthcare professional could change the planned order of topics, i.e. by using worksheets from other planned sessions. In this way, the intervention was made flexible to meet the individual participant's needs.

Prior to the interventions, the RNs and OTs were required to complete a three-day training programme to achieve certification. The training programme included lectures, practical training exercises, reflections and discussions. A reading list was supplied for the lectures. A manual describing the aim and content of the eight sessions, supplied with the underlying conceptual framework and research, supported the intervention personnel during the implementation of their individual intervention work. Group seminars led by members of the research team were organised for the intervention personnel (IP) during the study. The seminars were an arena for guidance and supervision, and they allowed the research team to reinforce IP training and compliance with protocol to promote intervention fidelity.

Table 4 Topical outline of the worksheets used in the intervention

1 Establish collaboration between stroke survivor and RN/CT, the story of what happened at stroke onset

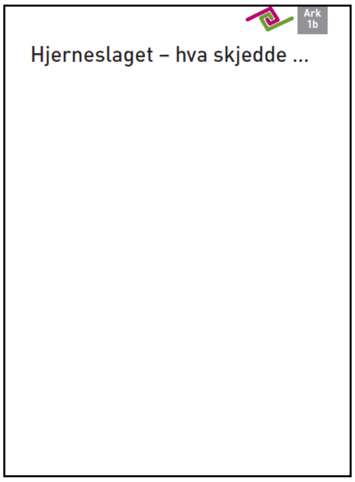

Ark 1a

Invitasjon til samarbeid

Samarbeidet handler om:

– **Ditt liv** med hjerneslag

– **Viktige områder** for at du skal ha det best mulig i en **ny situasjon**


Ark 1b

Hjerneslaget – hva skjedde ...

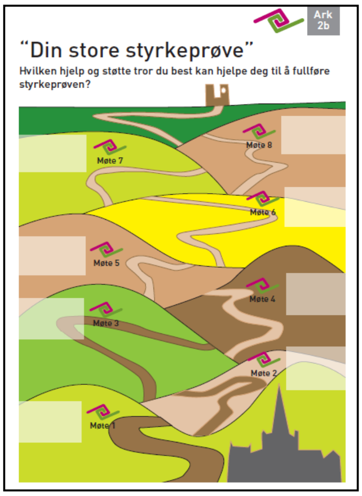

Ark 2a

Ditt liv før hjerneslaget:

(Her kan du skrive, tegne, markere viktige ting i livet ditt: Hendelser, personer, aktiviteter, verdier og interesser)

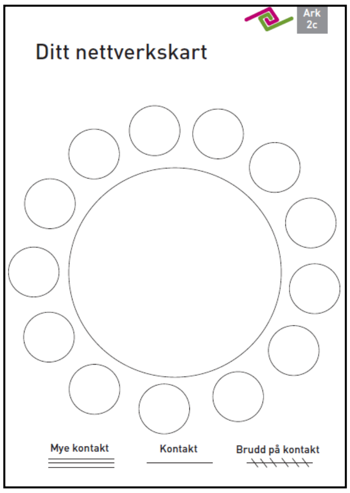
Viktig for deg:

2 Lifeline focusing on identity, values, social network, resources and goals


Ark 2b

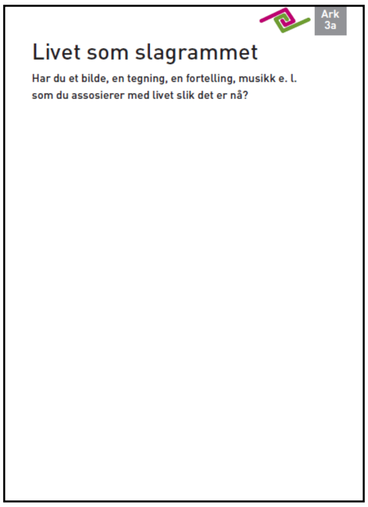
"Din store styrkeprøve"

Hvilken hjelp og støtte tror du best kan hjelpe deg til å fullføre styrkeprøven?


Ark 2c

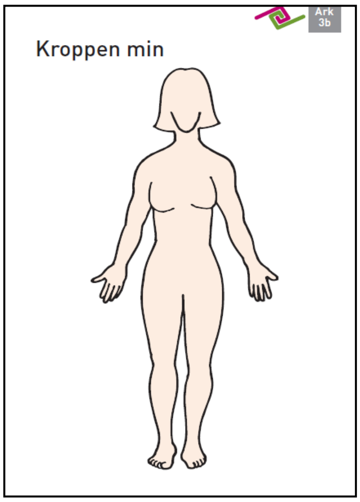
Ditt nettverkskart

3 Life after the stroke, focus on bodily changes, thoughts and experiences

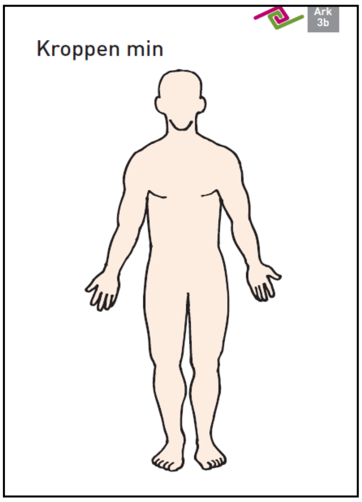

Ark 3a

Livet som slagrammet

Har du et bilde, en tegning, en fortelling, musikk e. l. som du assosierer med livet slik det er nå?

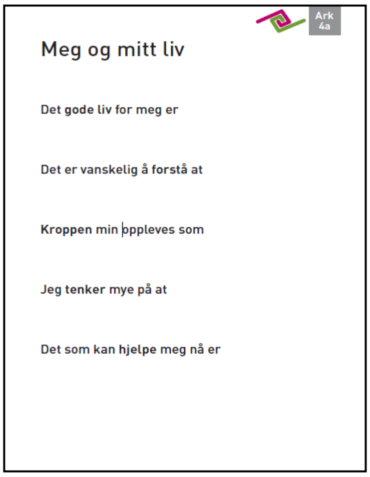

Ark 3b

Kroppen min


Ark 3b

Kroppen min

4 Life after the stroke, focus on daily life and emotions in everyday life


Ark 4a

Meg og mitt liv

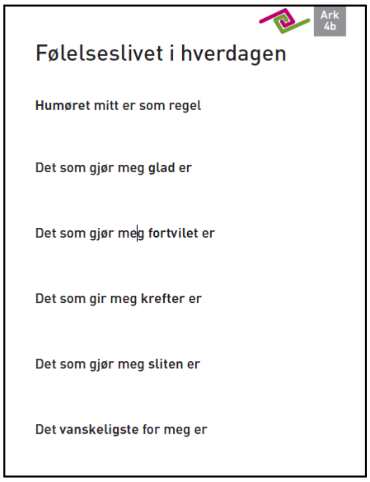
Det gode liv for meg er

Det er vanskelig å forstå at

Kroppen min oppleves som

Jeg tenker mye på at

Det som kan hjelpe meg nå er


Ark 4b

Følelseslivet i hverdagen

Humøret mitt er som regel

Det som gjør meg glad er

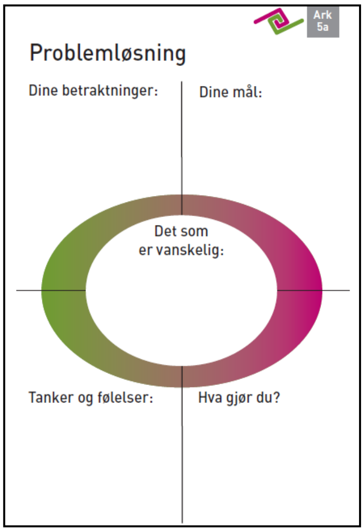
Det som gjør meg fortvilet er

Det som gir meg krefter er

Det som gjør meg sliten er

Det vanskeligste for meg er

5 Dynamic problem-solving with focus on resources in relationships, network, roles and activities



Problemløsning

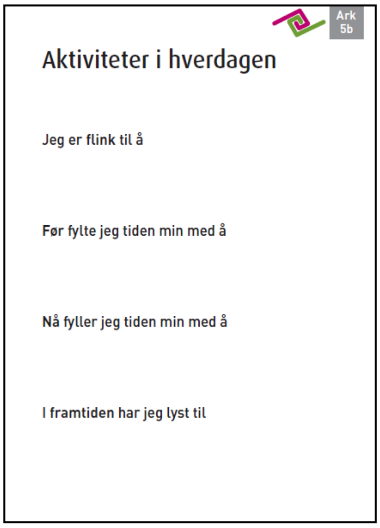
Dine betraktninger:

Dine mål:

Det som er vanskelig:

Tanker og følelser:

Hva gjør du?


Ark 5b

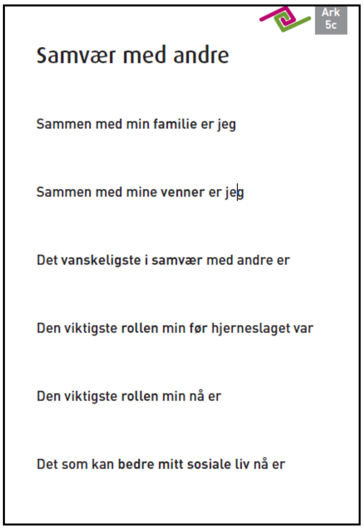
Aktiviteter i hverdagen

Jeg er flink til å

Før fylte jeg tiden min med å

Nå fyller jeg tiden min med å

I framtiden har jeg lyst til


Ark 5c

Samvær med andre

Sammen med min familie er jeg

Sammen med mine venner er jeg

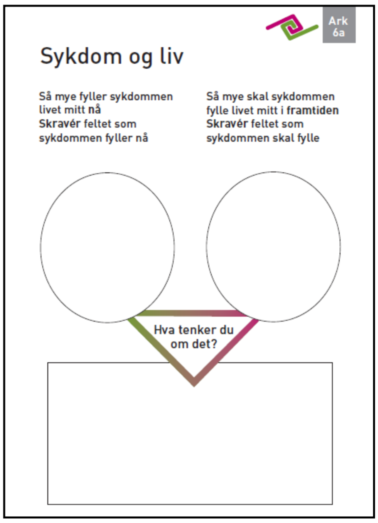
Det vanskeligste i samvær med andre er

Den viktigste rollen min før hjerneslaget var

Den viktigste rollen min nå er

Det som kan bedre mitt sosiale liv nå er

6 Establishing how the stroke affects life now and in the future, focus on coping strategies going forward

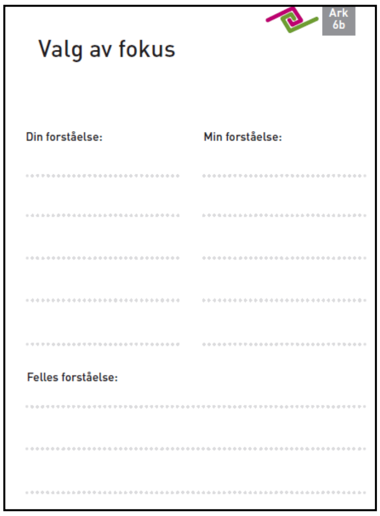


Sykdom og liv

Så mye fyller sykdommen livet mitt **nå**
Skravér feltet som sykdommen fyller nå

Så mye skal sykdommen fylle livet mitt i **framtiden**
Skravér feltet som sykdommen skal fylle

Hva tenker du om det?


Ark 6b

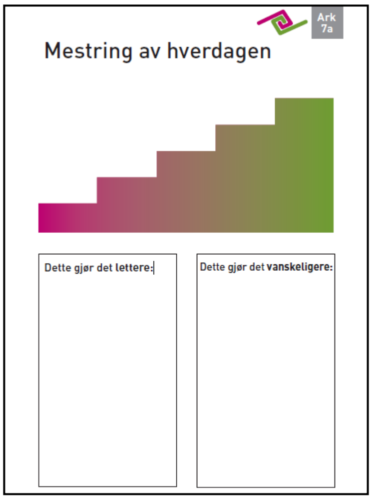
Valg av fokus

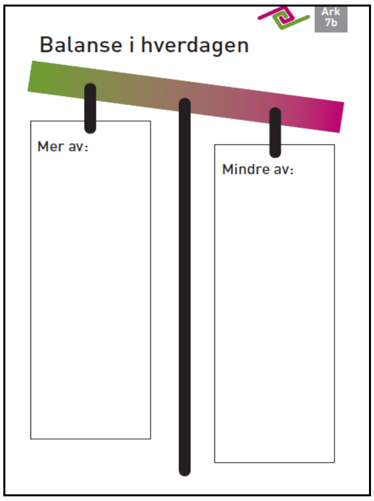
Din forståelse:

Min forståelse:

Felles forståelse:

7 Promoting coping in everyday life activities, encouraging balance in life





8 Concluding session focused on the stories told during the sessions and encouraging meaningfulness looking forward

There were no dedicated worksheets for Session 8

3.5 Data collection

3.5.1 Procedures

Participants were assessed prior to randomisation using structured outcome measures approximately one month post-stroke (T1). In addition, the data collector recorded the patient’s age, gender, living situation, education, work status, caring responsibilities, social support, comorbidities and rehabilitation services. At six months after the stroke, the T2 interview was conducted by a blinded assessor. The last assessment was at 12 months (T3) post-stroke. Prior to the assessments at T2 and T3, the participant received a text message with a reminder not to reveal the group allocation to the assessor. Any changes in the patient’s living situation or health status since the first assessment were also recorded at T2 and T3.

The data collector was either an RN or an OT. They received the written data collection procedure and individual training in administering each of the outcome measures. The assessment instruments were administered as a highly structured interview that was conducted in the participants’ homes or wherever the participants were at the time of the assessment. The assessor read the questions to the respondent and recorded the respondent’s answers on a web-based secure questionnaire using a tablet.

3.5.2 The primary outcome

The primary outcome for the trial was psychosocial well-being as measured by the GHQ-28. The GHQ was developed by Goldberg (109) and translated into Norwegian by Malt et al. (110). The original purpose of the instrument was to discover features that distinguish psychiatric patients from individuals who considered themselves healthy. The questionnaire particularly targets the grey area between psychological sickness and health (109). The focus is on breaks in normal function that lead to an inability to carry out one’s normal, healthy activities. The questionnaire is concerned with the manifestation of new phenomena of a distressing nature within the last few weeks.

The 28-question version of the GHQ was based on an EFA of the original GHQ-60 (109, 111). The GHQ-28 requests that participants indicate how their health in general has been over the past few weeks on a 4-point scale indicating, e.g. the following frequencies of experience: ‘not at all’, ‘no more than usual’, ‘rather more than usual’ and ‘much more than usual’. The scoring system applied in our study was the same as the original scoring system (109), a Likert scale with values ranging from 0 to 3 (112). The minimum score is 0, and the maximum is 84. Higher GHQ-28 scores indicate higher levels of distress, interpreted as lower levels of psychosocial well-being in this study. The continuous scale was applied in Papers 1 and 3, but in Paper 2 (and partly in Paper 3), the scale was dichotomised into normal (<5) or low (≥5) mood based on the scoring in a comparable study (19). The GHQ-28 has been used in other trials involving psychosocial stroke interventions (19, 113), but it had not previously been evaluated for reliability and validity in a Norwegian stroke population.

3.5.3 Secondary outcomes

The SAQOL-39g addresses general dimensions of health-related quality of life (HRQOL). Psychometric properties were evaluated in a previous study in which the instrument demonstrated good reliability, validity and responsiveness to change in the general stroke population (114). The SOC-13 had previously been applied in studies focusing on psychosocial well-being (115, 116). The SOC-13 has been found reliable and valid and is assumed to be cross-culturally applicable for measuring how people manage stressful situations and stay well (82). The Yale–Brown single-item questionnaire (Yale), taken from the Yale–Brown Obsessive Compulsive Scale (117), is a one-item instrument measuring the presence or absence of depression as experienced by the person (118). It has been validated as a measurement for depression in stroke patients (119). Table 5 provides an overview of outcome measurements and their level of measurement.

Table 5 Outcomes applied and level of measurement

Construct	**Instrument applied at T1, T2 and T3**	**Domains**	**Type of variable**
Primary outcome			
Mood	The General Health Questionnaire-28 (GHQ-28)	Twenty-eight–item general scale measuring psychological health and emotional distress. Four sub-scales (somatic symptoms, anxiety/insomnia, social dysfunction and serious depression). Scale from 0 to 84. Dichotomised into normal (> 5) or low (≤ 5) mood.	Continuous Binary
Secondary outcomes			
Health-related quality of life	The Stroke and Aphasia Quality of Life scale (SAQOL-39g)	Disease-specific quality of life scale measuring a patient's perspective of stroke's impact on physical, psychosocial and communication domains. Scale from 0 to 5.	Continuous
Sense of coherence	Sense of Coherence scale-13 (SOC-13)	Self-report questionnaire, 13 components, measuring the main concepts in the SOC theory: coherence, meaningfulness and manageability. Thirteen items scored on a Likert scale ranging from 1–5. Higher scores indicate a stronger SOC.	Continuous
Depression	Yale–Brown single-item questionnaire (Yale)	One yes/no question regarding feeling sad or depressed. Treated as dichotomous ʽyes' or ʽno'.	Binary
Fatigue	Lee's Fatigue Scale-5 (Lee-5) Fatigue Questionnaire (FQ-2)	A 1–10 scale assessing symptoms of fatigue. One yes/no question regarding feeling of fatigue; if yes, length of symptoms?	Continuous Binary

3.5.4 Outcomes as descriptors of the sample

Lee's Fatigue Scale (five items) (120, 121) and FQ-2 were chosen to measure fatigue in this study as descriptors of the sample. The five-item version of Lee's Fatigue Scale had previously shown satisfactory measurement properties and met criteria related to unidimensionality and ability to separate levels of fatigue, but in a different population than stroke (women with HIV/AIDS) (121). The NIHSS (108) is a well-established, reliable and valid assessment for measuring stroke severity in the acute stage of the stroke. The Ullevaal Aphasia Screening test (UAS) is a quick and valid aphasia screening that can be used by health professionals other than speech therapists to discriminate between aphasia and normal language (122).

3.6 Statistical methods

3.6.1 Preparation of data for analysis

Inspection of the data

The data were checked for outliers and floor/ceiling effect and evaluated for normality by examining histograms, frequency analyses and boxplots. All independent variables used in the regression models were tested for collinearity. When examining the dataset, as expected, we did find outliers and skewed data. Table 6 shows the distribution of the continuous variables.

The continuous variable of the GHQ-28 was treated as (approximately) normally distributed, but investigating the sub-factors individually revealed skewness in factors regarding social dysfunction and severe depression. In T1, several of the questions (c6, d3–d7) had a ceiling effect, with > 60% of the cases at the maximum of the scale. This limit was based on a limit set by another similar study (123). In T2, a ceiling effect was present in c1, c3, c5–c7, d2 and d4–d7. At T3, a ceiling effect was present in c3, c5–c7, d3 and d4–d7. (The questions are listed in the GHQ-28 in Appendix 4.)

The SAQOL-39g was analysed for both the original and log-transformed (2**) variables because of the non-normal distribution of the data. The results from the different analyses were compared, and no significant differences were discovered. To simplify the interpretation of the results, only outcomes from the original data analysis were presented and referred to in the papers.

Table 6 Distribution for the continuous variables

<table>
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GHQ-28</th><th>Distribution T2
GHQ-28</th><th>Distribution T3
GHQ-28</th></tr>
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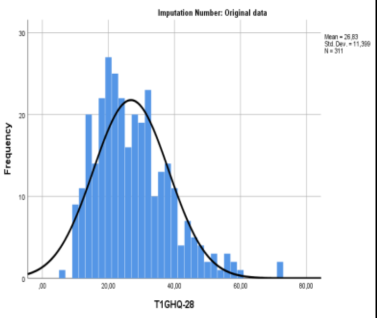

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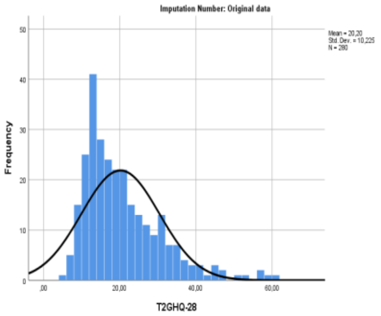

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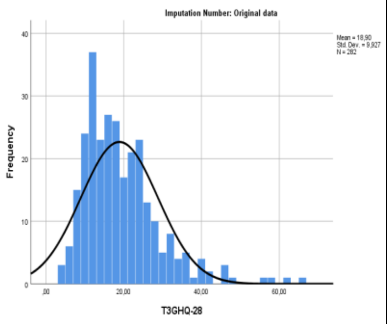

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SAQOL-39g</th></tr>
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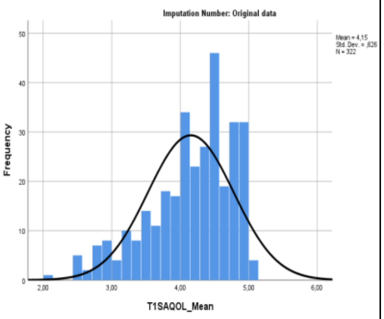

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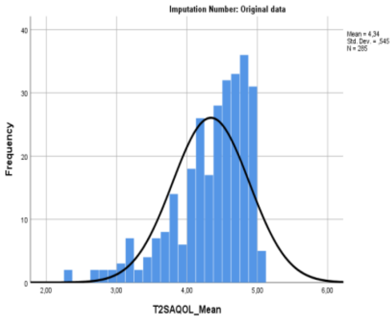

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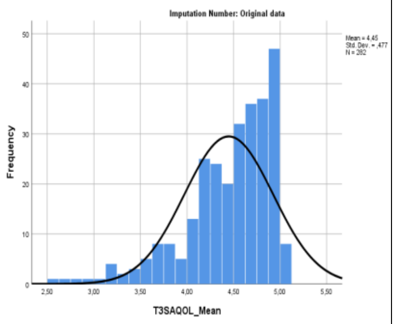

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SOC-13</th><th>Distribution T2
SOC-13</th><th>Distribution T3
SOC-13</th></tr>
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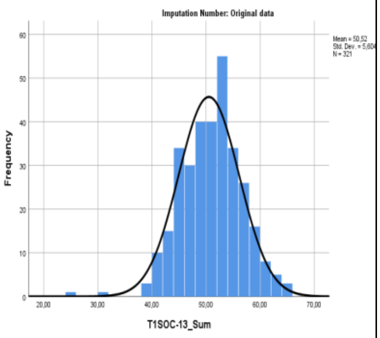

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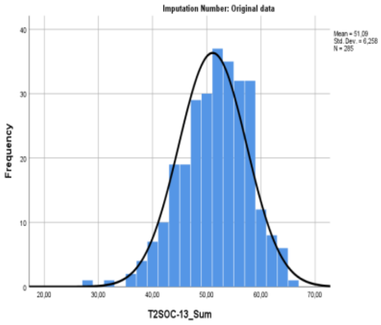

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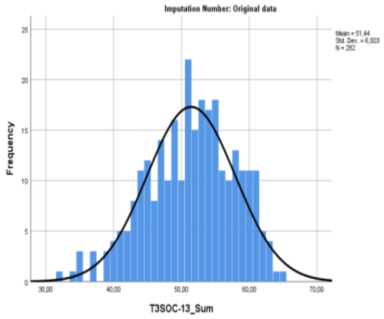

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Missing data and imputations

Eleven single values were missing, representing only 0.29% of the total items. Due to the data collection procedure with the tablet, it was technically impossible to proceed with the questionnaire if all questions were not answered. The missing values occurred if the participant refused to answer certain questions, in which case the assessor ticked ʽdo not want to respond'. The data set had 37 (11.5%) drop-outs between T1 and T2 and 40 (12.42%) at 12 months post-stroke (T3). The missing values were treated as missing at random (MAR). A common misunderstanding when treating the values as MAR is that the patients missing are literally missing at random. This is not the case. There might be systematic differences between the missing and observed values, and the missing values can therefore be explained by other observed variables (124). Missing data were imputed using multiple imputation by chained equations (MICE) in the Statistical Package for the Social Sciences (SPSS) (125, 126). The multiple imputation produced five data sets that were pooled across the five imputations based on Rubin's rule (127).

3.6.2 Statistical analysis

The majority of the analyses were conducted using SPSS version 25.0 for Windows (128). In addition, Monte Carlo principal component analysis (PCA) was used for the parallel analysis (129) as part of the factor analysis. The lavaan package version 0.5-23 (130) in R version 3.03 (131) was used to conduct the CFA and the analysis of measurement invariance. The statistical software R v3.6.1 (132) with package mitools v2.4 was used to pool the results across all five imputed data sets for the LMM analysis.

Descriptive analyses were conducted on all variables for the baseline characteristics. Frequency and percentages, means and standard deviation or median and interquartile range are presented as appropriate. Crosstabulations with McNemar's test for associations were used for the categorical and dichotomised variables, and paired-sample t-test or Wilcoxon signed-rank test was used for continuous data for investigating each randomisation. Between-group differences were analysed with independent-sample t-tests, chi-square tests or Mann–Whitney *U* tests, depending on the distribution of the variable.

Table 7 provides an overview of which statistical methods were applied for which outcome measurement. All statistical tests were intention-to-treat analyses performed as two-sided tests with a significance level of $\alpha = 0.05$.

Table 7 Statistical analysis applied in the study

Outcome measurement	**Statistical methods***
General Health Questionnaire-28 (GHQ-28)	Exploratory factor analysis Confirmatory factor analysis† Chi-square test McNemar's test Logistic regression Independent and paired-sample t-test Linear mixed model
The Yale Single Brown questionnaire (Yale)	Chi-square test McNemar's test Logistic regression
Stroke and Aphasia Quality of Life scale (SAQOL-39)‡	Independent- and paired-sample t-test Log transformation (2**) Multiple linear regression
Sense of Coherence (SOC-13)	Independent- and paired-sample t-test
Lee's Fatigue Scale	Independent- and paired-sample t-test
Fatigue Questionnaire-2 (FQ-2)	Chi-square test McNemar's test
Ulleval Aphasia Screening (UAS)	Mann–Whitney *U* test Wilcoxon Signed-Rank test
National Institutes of Health Stroke Scale (NIHSS)	Mann–Whitney *U* test Wilcoxon Signed-Rank test

*Conducted in SPSS unless stated otherwise. †Using the lavaan package for R. ‡The t-tests were applied to the log-transformed data.

3.6.3 Data analysis in Paper I

To evaluate the psychometric properties of the primary outcome measurement, an exploratory analysis was applied. The Kaiser–Meyer–Olkin (KMO) test was used to test the sampling adequacy for exploratory factor analysis, and Bartlett's test of sphericity was used to test equal variances. Cronbach's alpha was used to estimate the reliability of the instruments based on a required internal consistency of > 0.7 (133, 134).

The confirmatory factor analysis, using maximum likelihood estimation, was conducted to evaluate the model fit to the original construct (109). The analysis was performed by groups using data from both the baseline and six-month datasets. Several goodness-of-fit indicators were considered in the analyses. Comparative fit index (CFI) and Tucker–Lewis index (TLI) values of less than 0.95 indicated lack of fit, and values above 0.95 indicated good fit (135, 136). The root mean squared error of approximation (RMSEA) was set to be 0.06 or lower to indicate good fit (135).

Measurement invariance for two time points was evaluated by configural, metric and scalar invariance because investigating the three levels of invariance is recommended (137, 138). The most basic level of measurement invariance is configural invariance, which assumes that the items load on the same latent factors across groups, but factor loadings can vary. The second level, metric invariance, requires that all factor loadings are the same across groups. Scalar invariance is the strongest form of invariance; it implies metric invariance and, in addition, tests whether the intercepts are the same across the two time points. A change in CFI of less than 0.01 was considered evidence of invariance. This cut-off was based on the cut-off value used in a comparable study (139) and recommendations regarding cut-off criteria (135).

3.6.4 Data analysis in Paper II

A logistic regression with time points (T1 vs. T2) as the single independent variable was used to assess the odds of a normal mood (GHQ-28<5) and of not having depression (Yale) from T1 to T2 separately for each treatment group. The changes in the mean scores on the SAQOL-39g and SOC-13 from T1 to T2 in each treatment group were examined using paired-sample t-tests. To explore the group differences at six months, logistic regression analyses were used to analyse the effects of the intervention on mood (GHQ-28) and depression (Yale). A multiple linear regression analysis was applied to determine whether participating in the intervention statistically significantly predicted the participants' scores on the SAQOL-39g.

The SAQOL-39g analysis was conducted for both the original and log-transformed (2**) variables due to the non-normal distribution of the data. The results were compared, and no significant differences were discovered. To ease the interpretation of the results, only outcomes from the analysis of the original data are presented in the paper.

3.6.5 Data analysis in Paper III

In addition to exploring in-group and between-group differences as in Paper 2 (described in Section 3.6.4), a linear mixed model (LMM) was used to assess the primary outcome of psychosocial well-being at 12 months post-stroke. Due to the complexity of the final model, the loss of information when using the dichotomised ʽnormal mood' (GHQ-28≤ 5) endpoint instead of a continuous GHQ-28–based endpoint resulted in convergence issues when fitting the binary logistic mixed model as planned (1). We therefore decided to use the continuous sum score based on the Likert scoring of the GHQ-28 as the dependent variable for the 12-month LMM analysis.

Sensitivity analyses were conducted to explore whether the recruiting hospital, intervention providers' professional backgrounds or data collector ID should be included as random effects. The sensitivity analyses concluded that none of the additional variables should be included in the model because the model fit was better without including them.

3.7 Ethical considerations

Ethical approval was obtained from the Regional Committees for Medical and Health Research Ethics (2013/2047) and by the Data Protection Authorities (2014/1026), and the study was conducted in accordance with the ethical principles of medical research involving human subjects (140).

All patients gave their written consent before inclusion, following a written and oral explanation of the study. Competence to consent was evaluated individually by the recruiting personnel. If necessary, the inclusion was discussed with the interdisciplinary team, in particular for patients with cognitive challenges or aphasia.

Participation in the study was voluntary, and the participants were informed that they could cease participation at any time. The duration of the intervention was flexible, and the participants could cease participation prior to the maximum of eight intervention meetings. The assessment lasted from 30 minutes to two hours. If the participants felt tired during the assessments, the assessment could be paused and resumed after a break.

There were no assumed disadvantages from participating, and the participants could withdraw at any time from the study. However, focusing on psychosocial issues may be uncomfortable and upsetting, and it could be a potential trigger for psychological problems. If the patient showed signs of severe emotional distress during the interviews or intervention, the healthcare personnel were instructed to consider contacting the general practitioner, a family member or home care services.

4 Summary of results

4.1 Paper I

The General Health Questionnaire-28 (GHQ-28) as an outcome measurement in a randomized controlled trial in a Norwegian stroke population

4.1.1 Exploratory factor analysis

The KMO measure was 0.883, and Bartlett's test of sphericity reached statistical significance (p < 0.001), supporting the suitability for factor analysis. The Norwegian version of the GHQ-28 was internally consistent, as indicated by Cronbach's alpha values of 0.844, 0.881, 0.838 and 0.719 for the four sub-scales.

Inspection of the pattern matrix showed that all the anxiety and insomnia questions clustered together, accompanied by one question from the social dysfunction sub-scale and three from the severe depression sub-scale. Only four questions remained in the severe depression factor. The questions regarding somatic symptoms clustered together with six of the questions from the social dysfunction sub-scale. The three questions concerning headaches or having hot or cold spells formed their own category of somatic symptoms.

Overall, these results support a four-factor solution proposed by Goldberg and Hillier (109). However, the content of the factors does not support the original scale structure. The finding made it difficult to confirm the original factor composition by examining the results of the EFA alone. Therefore, the next step taken was to test, by means of CFA, the fit of the original structure in our stroke sample.

4.1.2 Confirmatory factor analysis

The comparative fit indices (CFI and TLI) did not reach the level of 0.95, which would indicate a good fit (135, 136). The RMSEA, which assesses the extent to which a model fits reasonably well in a population (141), exceeded the recommended fit index of 0.06 by 0.02. Since the CFA did not reach the strict cut-off for goodness of fit recommended in the literature, we could not confirm construct validity.

Measurement invariance at the two time points was confirmed. The fit of the least restrictive configural invariance model was compared with the results from the more restrictive metric and scalar invariance models. Neither the metric nor the scalar invariance model produced a change in the CFI of ≥ 0.01, which confirmed the metric and scalar measurement invariance within groups for the two time points. This means that the GHQ-28 questionnaire has comparable measurement properties at T1 and T2.

4.1.3 Conclusion

A sub-factor analysis based on the original factor structure of the GHQ-28 should be interpreted with caution. The factor composition is assumed to be affected by characteristics in the stroke population. Exploring the factor composition is recommended in the population in which sub-factor analyses of the outcome measurement are planned.

4.2 Paper II

Effect of a dialogue-based intervention on psychosocial well-being six months after stroke in Norway: A randomized controlled trial

4.2.1 Primary outcomes

After dichotomising the sum score of the GHQ-28 in normal or low mood, 99 of the 166 (59.6%) patients in the intervention group and 93 of the 156 patients (59.6%) in the control group had normal mood (GHQ-28<5) at six months. Compared with that at baseline, the proportion of participants with normal mood increased in both the intervention and control groups. After controlling for the baseline characteristics and recruitment centre, in the logistic regression model, no benefit of the dialogue-based intervention was observed over standard stroke care on mood at T2 (OR: 0.898, 95% CI: 0.54–1.50, *P* = 0.680). See Table 8 for details regarding statistics.

4.2.2 Secondary outcomes

Thirty-seven participants (22.3%) in the intervention group and 36 (23.1%) in the control group reported depression at six months in the Yale single-item questionnaire. After controlling for the baseline characteristics, the logistic regression model for depression (Yale) showed no effect of the intervention over standard stroke treatment at T2 (OR: 1.248, 95% CI: 0.64–2.41, *P* = 0.507). After controlling for the baseline characteristics in the multiple linear regression model, the analysis showed no benefit favouring the intervention over standard stroke care on the SAQOL-39g mean score (B = -0.026, CI: -0.13–0.08, *P* = 0.637) at six months. The SOC-13 did not significantly change from T1 to T2 in the intervention (T1: 50.6 (0.42), T2: 50.2 (0.57)) or control group (T1: 50.4 (0.46), T2: 50.5 (0.52)), and the between-group difference at six months was not statistically significant (p = 0.726).

4.2.3 Conclusion

Psychosocial well-being improved during the first six months after stroke in both arms of the trial, but a statistically significant benefit of the dialogue-based intervention compared to standard stroke care was not found.

4.3 Paper III

The 12-month effect of a dialogue-based intervention after stroke: A randomized controlled trial

4.3.1 Primary outcome

Both groups improved significantly on the primary outcome measure, GHQ-28, at 12 months relative to baseline. The proportion of participants reporting normal mood increased from 30.1% to 65.7% in the intervention group and from 29.5% to 66% in the control group; however, there were no between-group differences in psychosocial well-being at 12 months post-stroke (OR 0.98, 95% CI: 0.62, 1.57, p = 0.946). See Table 8 for details regarding statistics. The GHQ-28 sub-scale analyses of the factor structure discovered through the exploratory factor analysis in Paper 1 show that for the three sub-scales of somatic symptoms, anxiety and insomnia and social dysfunction, both groups reported statistically significant improvements from baseline to 12 months post-stroke, but not regarding severe depression. There were no between-group differences in any of the sub-scales of GHQ-28 at 12 months post-stroke.

The linear mixed model analysis (LMM)

This adjusted analysis confirmed the statistically significant decrease in GHQ-28 scores from baseline to six months (-5.65 points) and from baseline to 12 months (-6.49 points). Five explanatory variables had statistically significant effects influencing the GHQ-28 scores. Higher scores on the SOC-13 were associated with lower scores on the GHQ-28 (mean difference: -0.63 points). Other variables associated with lower GHQ-28 scores were reporting caring responsibilities (2.60 points), fatigue (4.09 points), depression (5.51 points) and additional comorbidities (1.79 points). The sample was unfortunately too small to conduct valid statistical sub-group analyses of these detected vulnerable sub-groups.

4.3.2 Secondary outcomes

There was no between-group difference in depression measured with Yale at 12 months post-stroke (OR 0.96, 95% CI: 0.55, 1.68, p value = 0.890). Sense of coherence appeared to be stable in both groups throughout the study trajectory from one to 12 months post-stroke. There was no statistically significant difference between groups on sense of coherence (SOC-13). The SAQOL-39g showed a statistically significant improvement in stroke-specific health-related quality of life from one month to 12 months post-stroke in the control group;

however, there was no within-group difference in the intervention group for the mean score. An investigation of the sub-scales of the SAQOL-39g showed statistically significant improvement in the physical domain in both groups. Additionally, there was a statistically significant improvement in the psychosocial domain in the control group. In the group comparison, there were no statistically significant differences between the intervention and control groups in SAQOL-39g at 12 months post-stroke.

4.3.3 Conclusion

The results support the notion that a higher sense of coherence is important in promoting psychosocial well-being. Patients reporting depressive symptoms, fatigue, comorbidities and caring responsibilities were prone to lower levels of psychosocial well-being. However, the results did not demonstrate that the participants in the intervention group experienced higher levels of psychosocial well-being and lower levels of depressive symptoms and anxiety than participants in the control group at 12 months post-stroke.

Table 8 Baseline, six- and 12-month primary and secondary outcomes by groups

Variable	**Intervention n = 166**					**Control n = 156**					***Between-group differences at 12 months (T3)***	
Primary outcomes	**T1**	**T2**	**T3**	**P Value***	**P Value§**	**T1**	**T2**	**T3**	**P Value***	**P Value§**		**P Value$^{¤}$**
GHQ-28 (<5)^{1} (N (%))	50 (30.1)	99 (59.6)	109 (65.7)	<0.001^{2}	<0.001^{2}	46 (29.5)	93 (59.6)	103 (66.0)	<0.001^{2}	<0.001^{2}	0.98 (0.62, 1.57)^{3}	0.946
GHQ-28 (sum)^{1} (Mean (SE))	25.9 (0.84)	21.2 (0.83)	20.6 (0.84)	<0.001^{4}	<0.001^{4}	28.5 (0.98)	21.5 (0.89)	19.9 (0.85)	<0.001^{4}	<0.001^{4}	-0.74 (-3.08, 1.60)^{5}	0.537
Somatic symptoms^{6}	2.4 (0.18)	1.8 (0.17)	1.8 (0.15)	0.007^{4}	0.002^{4}	2.8 (0.20)	1.8 (0.17)	1.9 (0.15)	<0.001^{4}	<0.001^{4}	0.10 (-0.31, 0.52)^{5}	0.618
Anxiety and insomnia^{6}	8.3 (0.43)	7.1 (0.40)	7.3 (0.43)	0.015^{4}	0.033^{4}	9.0 (0.49)	7.4 (0.46)	7.0 (0.45)	0.002^{4}	<0.001^{4}	-0.30 (-1.55, 0.95)^{5}	0.634
Social dysfunction^{6}	14.8 (0.38)	11.5 (0.40)	10.8 (0.36)	<0.001^{4}	<0.001^{4}	15.7 (0.42)	11.4 (0.38)	10.4 (0.32)	<0.001^{4}	<0.001^{4}	-0.36 (-1.32, 0.60)^{5}	0.457
Severe depression^{6}	0.5 (0.10)	0.7 (0.13)	0.8 (0.13)	0.034^{4}	0.030^{4}	0.9 (0.17)	0.9 (0.15)	0.6 (0.11)	0.798^{4}	0.103^{4}	-0.18 (-0.52, 0.17)^{5}	0.314
Secondary outcomes				**P Value***	**P Value§**				**P Value***	**P Value§**		**P Value$^{\|}$**
Feeling sad or depressed (Yale) (N(%))^{1}	29 (17.4)	37 (22.3)	38 (22.9)	0.318^{2}	0.279^{2}	43 (27.6)	36 (23.1)	37 (23.7)	0.349^{2}	0.444^{2}	0.96 (0.55, 1.68)^{3}	0.890
Sense of coherence (SOC-13) (Mean (SE))^{1}	50.6 (0.42)	50.2 (0.58)	50.6 (0.62)	0.489^{4}	0.936^{4}	50.4 (0.47)	50.5 (0.52)	51.0 (0.56)	0.814^{4}	0.268^{4}	0.43 (-1.09, 1.94)^{5}	0.581
Quality of life (SAQOL-39g)^{1} (Mean (SE))	4.30 (0.04)	4.38 (0.05)	4.36 (0.04)	0.080^{4}	0.077^{4}	4.24 (0.05)	4.37 (0.04)	4.43 (0.04)	0.003^{4}	<0.001^{4}	0.06 (-0.04, 0.17)^{5}	0.247
Physical domain^{1}	4.24 (0.07)	4.52 (0.06)	4.50 (0.05)	<0.001^{4}	<0.001^{4}	4.21 (0.08)	4.52 (0.05)	4.57 (0.05)	<0.001^{4}	<0.001^{4}	0.06 (-0.07, 0.20)^{5}	0.364
Communication domain^{1}	4.75 (0.04)	4.76 (0.03)	4.73 (0.04)	0.742^{4}	0.542^{4}	4.74 (0.05)	4.79 (0.03)	4.79 (0.04)	0.263^{4}	0.338^{4}	0.06 (-0.05, 0.16)^{5}	0.271
Psychosocial domain^{1}	3.90 (0.06)	3.86 (0.07)	3.85 (0.07)	0.626^{4}	0.501^{4}	3.76 (0.06)	3.79 (0.08)	3.93 (0.07)	0.691^{4}	0.017^{4}	0.07 (-0.11, 0.25)^{5}	0.447

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[1] Reporting pooled results of imputed data,[2] logistic regression, p-value, [3] logistic regression, (OR (95% CI)), [4] paired-sample t-test, p-value, [5] independent-sample t-test (mean difference (95% CI)), [6] reporting pooled results of imputed data (by factor structure discovered in Sub-study I), * within group differences from T1 to T2, § within group differences from T1 to T3, $^{\|}$ between group differences at T3.

5 Discussion

5.1 General discussion of the main findings

The overall objective of this dissertation was to evaluate the effect of a dialogue-based psychosocial intervention in a randomised controlled trial. The rationale for the intervention was that psychosocial challenges are common after stroke, and they affect the rehabilitation and recovery process. However, previous studies had not provided clear recommendations on how to address these challenges in a way that was effective and feasible for application in a Norwegian community setting.

It was hypothesised that dialogue-based sessions inspired by guided self-determination provided in the early adjustment phase following a stroke could lead participants to a higher level of sense of coherence, psychosocial well-being and health-related quality of life and less depression and anxiety.

Contrary to our hypothesis, the results did not demonstrate that the participants in the intervention group experienced higher levels of psychosocial well-being (GHQ-28) and health-related quality of life (SAQOL-39g). The level of sense of coherence was stable, and the participants in the intervention group did not have a lower level of depression and anxiety than the participants in the control group.

The following sections discuss the possible reasons for the results. The first part of this chapter provides a general discussion of the underlying theoretical assumptions of key components of what promotes well-being. In addition, other areas investigated in previous studies, such as timing, target group and the outcome measure to target different aspects of psychosocial well-being, are discussed. In the second section, methodological considerations, including the reliability, validity and responsiveness of the primary outcome measurement, are discussed, and the generalisability of the findings is addressed.

5.1.1 Theoretical assumptions about what promotes psychosocial well-being

Sense of coherence

We assumed that an important ingredient in the intervention would be supporting the participants' perception of their lives as comprehensible, manageable and meaningful and giving them a greater degree of understanding of how to manage and find meaning in their new existence following their stroke (1, 2). The intervention aimed to strengthen the sense of coherence by supporting the participants in the coping process after stroke. In the second sub-study, we found that higher SOC-13 scores increased the odds of normal mood. This finding was strengthened by the results of the linear mixed model analysis in Sub-study III. Higher SOC-13 scoring was a statistically significant factor that contributed to a lower (better) score on the GHQ-28. This indicates that a higher sense of coherence had a protective effect on the adverse experiences a stroke may impose and supports the previous knowledge of a correlation between sense of coherence and quality of life (83, 142). However, since we also hypothesised that sense of coherence could be strengthened if events and life situations were perceived as understandable, manageable and meaningful, an important factor we wanted to evaluate was whether the sense of coherence could be strengthened through the intervention.

Antonovsky (143) claimed that the sense of coherence is a stable entity that is developed and formed in childhood and early adulthood, stabilising around the age of 30. Later studies have shown that it increases with age (82) and that interventions can influence the level of sense of coherence. Forsberg et al. (144) found that improving physical health with lifestyle programmes, in addition to increased physical health, improved the sense of coherence in patients with psychiatric disabilities. Furthermore, in their study, Langeland et al. (145) found a significant increase in the SOC after climate therapy for people with rheumatic challenges. In the analysis of this study, the scorings on the outcome measurement, SOC-13, were approximately equal regardless of the intervention and stable across all three time points. The lack of differences within groups over time and between the intervention and control groups suggests that the intervention did not influence the level of sense of coherence in our study.

Even though the intervention was encouraged to be individualised, this was limited by the talk-based frame of the intervention addressing psychosocial challenges post-stroke. Several of the worksheets and questions were problem-oriented. According to Sales et al. (146), addressing factors that do not pose a challenge may lead to more concern. They found that narratives about a negative past experience were associated with increased depressive symptoms and argued that for certain individuals, efforts to find meaning through narratives may not be psychologically healthy. Considering the findings of Sales et al., it is possible that the intervention may have led to increased instead of decreased worry for some participants.

The three studies previously described that documented effects of their psychosocial interventions (19, 65, 76) differed in their approach by not addressing concrete problematic areas unless the participant addressed them. Motivational interviewing applied by Watkins et al. aimed to promote self-efficacy—as opposed to problem-solving—and the shift to a healthier lifestyle (19). The patients raised the issues they wanted to discuss instead of having topics suggested for each meeting or an overall focus on issues related to potential psychosocial challenges. Graven et al. (65) provided follow-up according to needs from a list of alternative interventions. The goals were set by the participants during follow-up, which ensured that the personnel only provided services to meet the specifically expressed needs of the participant. In Hill et al.'s (76) intervention, even though the intervention was problem-solving therapy, the intervention had a future- and goal-oriented approach focusing on the problem in the moment as opposed to connecting the current event to the past.

5.1.2 Timing of the intervention

Based on the development and feasibility of our intervention (2, 3), it was assumed that support during the first six months after stroke was the optimal starting point of the intervention to strengthen coping skills and promote psychosocial well-being. However, it is important to consider whether the extra attention given to the psychosocial issues in the intervention group came at an appropriate time in the participants' stroke recovery, as well as whether there may be a more appropriate time for such an intervention.

In studies of the illness trajectory after stroke, a focus on physical recovery was commonly more pronounced initially (39, 147), and the first six months after stroke are characterised by the expectation of progress and a particular focus on regaining function and practical adjustments. In Eilertsen et al.'s (39) study, the illness trajectory after stroke was described as being comprised of four adjustment phases that the respondents passed through during the first months post-stroke. The first phase is the trajectory onset, characterised by surprise and suspense. The second is the initial rehabilitation, which typically lasts from a few days up to three months and during which the major focus is on regaining the lost functions. The third phase is continued rehabilitation. Typically, the third phase starts when the patient leaves in-house rehabilitation services and needs to develop a daily structure that allows him or her to accomplish his or her daily activities. During the second half-year following the stroke, things settle down, and this fourth stage is called the semi-stable phase. It is characterised by a reflection on health, values and potential new meaning in life (147).

In the first six months post-stroke, individuals experience challenges that are directly caused by the stroke (29) or result indirectly from the side effects of medications, such as headache

(148, 149). They experience the challenges as temporary and expect that the problems will resolve spontaneously or with hard work. The participants may have been more focused on the recovery and practical parts of their adjustment than those of a psychosocial nature in the first six months post-stroke.

5.1.3 Target group

In the LMM model in the third sub-study, we found that four sub-groups were especially vulnerable to having a higher GHQ-28 score and lower psychosocial well-being. Participants who reported depression, fatigue, comorbidities and having additional burdens of caring responsibilities at baseline showed reduced psychosocial well-being. Nevertheless, we did not find support in the statistical analysis that our intervention benefitted any of these sub-groups regarding psychosocial well-being. For example, investigating the scoring on GHQ-28 at the group level revealed that the scoring was approximately the same between the intervention and control groups (e.g. participants with comorbidities in the intervention group scored 19.8 and the control group 19.3 on the GHQ-28 at T3 (a non-statistically significant difference)).

Previous studies have indicated that the severity of the stroke sequelae is an indicator of an increased risk of psychosocial problems or depression (36, 150) and that patients with disability, a history of depression, cognitive problems, poor social networks and anxiety are at risk of experiencing psychosocial challenges post-stroke (151). Another known group at risk is people experiencing aphasia (90). Unfortunately, this study included too few patients from these sub-groups to conduct valid sub-group analyses. It was difficult to include the patients with the most severe stroke. Even if the intervention was open for individualisation, a prerequisite for participation included being able to complete the assessments, which consisted of approximately 100 questions. This was not feasible for all patients.

5.1.4 Different aspects of psychosocial well-being

Psychosocial well-being is a subjective phenomenon, and finding the optimal outcome measurement that is appropriate for detecting changes is challenging. The choice of GHQ-28 as the primary outcome measure to target psychosocial well-being enabled us to make comparisons to a comparable study (19, 113), but in retrospect, it may not have been the most suitable outcome measure to detect all the types of changes we targeted in our intervention. Psychosocial well-being was thought to consist of the four elements Næss described (58) (see Section 1.5.1 for details). One could argue that the first element concerning the respondent’s basic mood of contentment and absence of pervasive feelings of sadness was primarily measured. Even though the third sub-factor on social dysfunction in the GHQ-28 addresses factors regarding participation and engagement in meaningful activities to some degree and one factor in the SAQOL-39g measures the patient's perspective of the stroke's impact on psychosocial domains, there was a clear overweight of questions in the outcome measurements related to how the participants feel physically and emotionally. Consequently, aspects presumed to affect psychosocial well-being, such as engagement and participation in meaningful activities, social relationships, self-acceptance, a feeling of usefulness and belief in one's abilities, were not specifically measured.

Compared to the 14 studies explored in Section 1.5.2, the studies varied in terms of what aspect of psychosocial well-being was targeted and evaluated. All the studies assessed symptoms of anxiety and/or depression, but health-related quality of life, mood and well-being were also assessed in several of the studies (19, 61, 62, 64-67, 69, 70, 72, 76). Other aspects evaluated in some of the studies were participation (67), stress (70), stroke impact (70), coping (72), problem-solving skills (76) and satisfaction with services (62, 71, 76).

The existence of a wide variety of outcome measures aiming to evaluate different aspects of psychosocial well-being is both an asset and a challenge. The variety provides the researcher with alternatives in the evaluation of effects, since interventions are usually complex and may have diverse outcomes. However, it challenges comparison across studies and indicates a lack of consensus in the research community about how to evaluate psychosocial interventions and what aspect of psychosocial well-being to target.

5.2 Methodological considerations

Evaluation of a complex intervention is complicated due to all the components in the intervention and the intervention's interaction with the context of implementation. This section discusses methodological considerations and challenges regarding the study design and procedures, followed by an evaluation of the reliability, validity, responsiveness and generalisability of the findings.

5.2.1 Study design and methods

One strength of the main project was the systematic development and feasibility testing of the intervention prior to the RCT as recommended by the UK MRC framework for the development and evaluation of complex interventions (105). A comprehensive process evaluation was conducted alongside the trial. This was an important advantage in documenting the trial implementation and understanding the trial outcomes. Other strengths were conducting the study according to the protocol (1) with high intervention fidelity (107) and following the CONSORT guideline for reporting a randomised controlled trial (101).

A number of obstacles caused delays in the enrolment, e.g. other research projects had priority for including patients in one of the centres, too many things were going on in the patients' lives during a very limited hospital stay or the patients were too sick to make a decision about participating in a research project within the first month after stroke. Even though these obstacles caused subsequent delays, the sample reached adequate size to achieve statistical power by using an additional year to recruit a sufficient number of participants.

5.2.2 Evaluating the effect

In the selection of an assessment tool, multiple psychometric properties must be considered (152, 153). Measures need to be reliable (internally consistent and stable over time), valid (measuring the intended characteristics) and responsive (able to detect change). Methodological considerations regarding these factors will be discussed in the next sub-sections.

Reliability

Internal consistency and stability over time were measured as part of the first study of psychometric properties of the GHQ-28. An outcome measure is typically evaluated for internal consistency using Cronbach's alpha (154, 155). The Cronbach's alpha value was acceptable with alpha values of 0.844, 0.881, 0.838 and 0.719 for the four sub-scales (156).

For T1 and T2, measurement invariance was confirmed by all three levels of invariance investigated for the primary outcome measurement (156), which is an indication that the same construct has been measured at both time points and there is no indication of a response shift bias (157). A response shift is a change in the meaning of one's self-evaluation due to a change in the internal standards of measurement or values, or alternatively, a redefinition of the construct. This can cause a measurement error affecting the researcher's ability to make accurate and meaningful comparisons between groups across time points.

Evaluating measurement invariance between T1 and T3 using the same procedure, as in Sub-study I, also confirmed both configural and metric invariance between T1 and T3. However, according to Bialosiewicz et al. (158), the ability to justify mean comparisons across time is established by also attaining scalar invariance. Scalar invariance builds on metric invariance by requiring the item intercepts to be equivalent across administrations. In the measurement invariance testing of the T1 and T3 responses, scalar invariance was not confirmed. The comparable fit indices changed by more than the recommended 0.010 (change: 0.014). Table 9 shows the fit indices.

Table 9 Overall fit indices from the measurement invariance tests at T1–T3

Measurement invariance model*	CFI	TLI	RMSEA
Configural	0.805	0.785	0.080
Metric	0.798	0.786	0.080
Scalar	0.784	0.779	0.081

*CFI: comparable fit index. TLI: Tucker–Lewis index. RMSEA: root mean square error of approximation.

Non-invariance of intercepts may be indicative of potential measurement bias and suggests that there are forces influencing how the participants respond to items across administrations, with participants systematically rating items either higher or lower at each administration time (158). In this study, if we consider the strictest form of measurement invariance, this introduces a potential bias in the interpretation of changes between T1 and T3. However, it cannot explain the statistically different changes in both groups from T1 to T2 or the neutral results between the intervention groups at T2 and T3. Also, the change in the GHQ-28 was most prevalent between T1 and T2, with all levels of measurement

Validity

Construct validity

There were challenges regarding the validity of the primary outcome in this study. The construct validity of the primary outcome measure, GHQ-28, was not confirmed in Sub-study I (156), and this drew attention to potential challenges when using the sub-factors of the GHQ-28 to evaluate the effect of an intervention in a stroke population.

Originally, the GHQ-28 was intended for studies in which investigators were seeking more information about emotional distress than that provided by a single severity score (109). In the exploratory factor analysis, all three questions regarding pain and discomfort formed an independent category instead of being included with the other questions about somatic symptoms. Pain and headache are complications that can occur after a stroke (149), but they may also be a side effect of medications used as secondary prevention following a stroke (148). Thus, physical pain and discomfort may not necessarily be related to psychological distress, and the symptoms will pass without further treatment within the first weeks or months. Questions originally categorised in the severe depression sub-category were clustered with questions originally categorised under anxiety. This result was not surprising since anxiety and depression are correlated post-stroke (159, 160); however, it challenges the evaluation of anxiety and depression separately. Four items from the original somatic symptoms factor and six items from the social dysfunction factor (156) formed one factor. Feelings of being ʽperfectly well and in good health' increased, and feelings of being ʽrun down and out of sorts' or of being ʽill' improved as expected during the first weeks or months after the stroke and may be due to the natural recovery after a stroke.

Internal validity

Internal validity is one of the most important properties of scientific studies and is an important concept in reasoning about the strength of evidence, but several factors may influence and threaten a study's internal validity. The intervention period in our study coincided with a period in which brain plasticity and spontaneous functional recovery may be considerable (161). It also overlapped with a period in which the rehabilitation efforts are substantial in the Norwegian health services (43). The psychosocial intervention provided to the intervention group may have a limited effect in this context since both groups also received rehabilitation efforts either in the hospitals, rehabilitation units or the community as part of the standard stroke care.

A focus on empowerment and self-management is a possible factor affecting well-being (14); however, empowerment and self-management are also highly applied components in the standard rehabilitation interventions following stroke in Norway (162). Other factors such as information provision (11, 13) and having a liaison (12) are also commonly included in the standard stroke treatment in Norway. Physical activity and an individualised, goal-oriented approach, as emphasised as an important factor in the intervention evaluated by Hill et al. (76), are encouraged by the Norwegian stroke guideline (43) and are implemented as part of stroke rehabilitation services in many of the municipalities in addition to encouraging participation in activities in general. Although these elements were not a part of our intervention, they are potential factors affecting psychosocial well-being that participants received as part of the standard stroke treatment.

We registered which rehabilitation services the participant received at one, six and 12 months after the stroke and discovered that the rehabilitation services provided were comprehensive. At baseline, 68.7% of the intervention group and 63.5% of the control group received one or more rehabilitation services. At 12 months post-stroke, the proportion receiving one or more rehabilitation services was 42.3% in the intervention group and 42.1% in the control group. The services could include speech and language therapy, psychologist sessions or home nursing care, but the most frequently reported follow-up was physical therapy (at one month post-stroke, intervention: 59.0%, control: 56.4%; and at one year post-stroke, intervention: 24.6%, control: 29.3%). This high percentage of participants with follow-up from physical therapists was unexpected based on the awareness that the majority of participants had minor physical challenges post-stroke. Several factors could explain this. One is comorbidity; we do not know for sure that the patients received physical therapy due to the stroke. It may have been related to challenges due to other conditions, since approximately 80% of participants had some form of comorbidity. Another possible explanation is the availability of services, since physical therapy is the most common therapy available in the municipalities.

Nevertheless, Watkins et al. did succeed in finding a statistical significant difference between the amount of participants with normal and low mood. The amount of follow-up as part of standard stroke treatment in Watkins et al.’s study is unknown, but the clinical guidelines for stroke rehabilitation (163) resemble the guideline in Norway (43). However, comparing the number of participants in the control group between baseline and one year in the two studies, we found that in the control group, the amount of participants with normal mood in Watkins et al.'s study only increased from 37.6% to 42.6% (113) compared to 29.5% to 66% in our study. This drew attention to the potential effect of the research design. While Watkins et al. used mailed questionnaires as their first choice, this study applied face-to-face assessments. The choice ensured high compliance and little missing data, but it caused some challenges. The qualitative interviews with the control group participants that were included in the process evaluation alongside this RCT (after the 12-month assessment was finished) indicated that the assessment interviews influenced some of the participants (164). Participants emphasised that the assessment interviews served as a safety net, enhanced their awareness and understanding, facilitated their adjustment after stroke and encouraged them to seek support. The standardised interviews were also useful for measuring progress. More information on this will be published in a separate paper (164).

5.2.3 Responsiveness and generalisability

The statistically significant change in scoring between T1 and T2/T3 for both the intervention and control groups indicated that the GHQ-28 is sensitive to change. Responsiveness, or the ability to detect change over time, rests on the assumption that respondents' interpretations of a construct remain constant over time (163). This was confirmed in the measurement invariance analysis of the first two time points, T1 and T2, at which most of the improvement occurred. The extent to which the results of the study can be generalised to all stroke patients might be questioned. Patients with stroke or aphasia were difficult to include due to early enrolment and difficulties in obtaining informed consent. In addition, we struggled to include other patients known to be at risk of psychosocial problems such as those with severe stroke and cognitive impairment (165, 166). Consequently, even though the sample was sufficient to ensure statistical power and large enough considering the comprehensive intervention, the sample was small relative to the heterogeneity of the whole stroke population. However, as for many similar studies, including the three studies referred to with a documented effect of the intervention (19, 65, 76), the patients with severe stroke, aphasia and severe cognitive impairments are commonly not represented. Due to medical improvements in acute stroke treatment, the majority of stroke survivors in Norway have minor or moderate stroke symptoms as measured by the NIHSS (25, 27). This makes our sample, nevertheless, representative of the largest group of stroke patients admitted to hospital in Norway (25). In addition, it is important to note that a so-called minor stroke may still have major consequences in the stroke survivor's life.

6 Conclusions and future perspectives

6.1 Conclusions

A heightened sense of coherence had a protective effect against a lower level of psychosocial well-being, but addressing psychosocial challenges did not strengthen the participants' sense of coherence or psychosocial well-being. The hypothesis that the participants in the intervention group would experience improved mood, a higher level of health-related quality of life and less depression and anxiety through the dialogue-based, guided, self-determination-inspired sessions was not confirmed statistically.

Several factors might have contributed to this result. One factor concerns the timing. Was the timing of the intervention, from one to six months post-stroke, right in relation to the participants' focus? During the first six months post-stroke, the focus is typically more on regaining physical function, and the challenges are expected to be temporary. The patients do not yet have experience with longer-lasting or more permanent changes.

Patients reporting depressive symptoms, fatigue, comorbidities and caring responsibilities were prone to a lower level of psychosocial well-being. However, even though we identified patient groups that were vulnerable to psychosocial challenges, we did not determine that any of these sub-groups benefitted from the intervention.

All the measures that have been applied in previous studies aiming to evaluate different aspects of psychosocial well-being challenge comparison across studies and indicate a lack of consensus in the research community about how to evaluate psychosocial interventions and what aspect of psychosocial well-being to target in stroke rehabilitation and research.

Methodologically, the evaluation of this kind of complex intervention in the first six months was challenging, particularly regarding validity and potential control condition bias. It is necessary to consider whether the narrative approach was a sufficient add-on, since a substantial number of the participants had follow-up as part of standard stroke treatment and rehabilitation. Finding the perfect outcome measurement in this complex phase of rehabilitation is difficult because it will be affected by the characteristics of the sample population and the natural recovery post-stroke.

6.2 Future perspectives

Studies inspired by the MRC guidance, including development and feasibility testing of an intervention before conducting a full scale RCT, are time-consuming. The process preceding the RCT phase of the main project started in 2007. The rehabilitation of stroke patients has improved since then due to healthcare reforms and the implementation of the national clinical guideline for stroke treatment. This improvement added challenges with internal validity in the chosen timeframe for the intervention. Future studies are recommended to direct further attention to the importance of piloting this kind of randomised controlled trial and testing the feasibility of the outcome measures, as well as directing particular attention to potential control condition bias.

It was challenging to recruit groups of patients known to be vulnerable like those with severe stroke, cognitive challenges and aphasia. There is still a need to explore the needs of these vulnerable groups in addition to the groups identified through this study and explore if any of the sub-groups may benefit from a dialogue-based intervention.

Last, it is necessary to explore what outcome measurement is the best to detect what aspects of psychosocial well-being that should be targeted in an intervention and to capture the effect of such an intervention. It is recommended that future research focus on aspects that were not explicitly evaluated in this trial but are presumed to affect psychosocial well-being, such as relationships, engagement and participation in meaningful activities.

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Errata

Original Papers

I. Hjelle EG, Bragstad LK, Zucknick M, Kirkevold M, Thommessen B, Sveen U. The General Health Questionnaire-28 (GHQ-28) as an outcome measurement in a randomized controlled trial in a Norwegian stroke population. *BMC Psychol*. 2019 Mar 22;7(1):18. doi: 10.1186/s40359-019-0293-0

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III. Bragstad LK, Hjelle EG, Zucknick M, Sveen U, Thommessen B, Bronken BA, Martinsen R, Kitzmüller G, Mangset M, Kvigne KJ, Hilari K, Lightbody CE, Kirkevold M, (2019). The 12-month effects of a dialogue-based intervention after stroke: A randomized controlled trial. Submitted to *Clinical Rehabilitation* Sept 24, 2019, In review.

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RESEARCH ARTICLE Open Access

The General Health Questionnaire-28 (GHQ-28) as an outcome measurement in a randomized controlled trial in a Norwegian stroke population

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Abstract

Background: Several studies have documented the variety of post-stroke psychosocial challenges, which are complex, multifaceted, and affect a patient's rehabilitation and recovery. Due to the consequences of these challenges, psychosocial well-being should be considered an important outcome of the stroke rehabilitation. Thus, a valid and reliable instrument that is appropriate for the stroke population is required. The factor structure of the Norwegian version of GHQ-28 has not previously been examined when applied to a stroke population.
The purpose of this study was to explore the psychometric properties of the GHQ-28 when applied in the stroke population included in the randomized controlled trial; "Psychosocial well-being following stroke", by evaluating the internal consistency, exploring the factor structure, construct validity and measurement invariance.

Methods: Data were obtained from 322 individuals with a stroke onset within the past month. The Kaiser-Meyer-Olkin (KMO) test was used to test the sampling adequacy for exploratory factor analysis, and the Bartlett's test of sphericity was used to test equal variances. Internal consistency was analysed using Cronbach's alpha. The factor structure of the GHQ-28 was evaluated by exploratory factor analysis (EFA), and a confirmatory factor analysis (CFA) was used to determine the goodness of fit to the original structure of the outcome measurement. Measurement invariance for two time points was evaluated by configural, metric and scalar invariance.

Results: The results from the EFA supported the four-factor dimensionality, but some of the items were loaded on different factors compared to those of the original structure. The differences resulted in a reduced goodness of fit in the CFA. Measurement invariance at two time points was confirmed.

Conclusions: The change in mean score from one to six months on the GHQ-28 and the factor composition are assumed to be affected by characteristics in the stroke population. The results, when applying the GHQ-28 in a stroke population, and sub-factor analysis based on the original factor structure should be interpreted with caution.

Trial registration: ClinicalTrials.gov, NCT02338869, registered 10/04/2014.

Keywords: Factor analysis, Psychometric properties, Stroke, Quality of life

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Background

Stroke may cause a number of psychosocial challenges that affect a patient's rehabilitation and recovery [1, 2]. Several studies have documented the variety of post-stroke psychosocial challenges, which are complex and multifaceted and may have different trajectories [3, 4]. Due to the consequences of these challenges for stroke rehabilitation, psychosocial well-being should be considered an important outcome of rehabilitation.

One instrument that has been widely used for screening and assessing mental symptoms and psychosocial well-being is the General Health Questionnaire (GHQ). The purpose of the instrument is to discover features that distinguish psychiatric patients from individuals who consider themselves to be healthy, and the questionnaire particularly targets the grey area between psychological sickness and health [5]. Based on the original 60-item version, several versions of GHQ have been constructed. The GHQ-28 was developed by Goldberg and Hillier in 1979 and is based on an exploratory factor analysis (EFA) of the original GHQ-60 [6].

The GHQ-28 is currently being applied as the primary outcome measurement in a study evaluating the effect of a psychosocial intervention on well-being after stroke [7]. The present study was part of this multicentre, prospective, longitudinal, randomized controlled trial.

The GHQ-28 is a self-administered instrument and is considered appropriate for research purposes [5]. This scaled version was intended for studies in which the investigators seek more information than that provided by a single severity score. In the construction of the GHQ-28, items were selected to cover four main areas: somatic symptoms, anxiety and insomnia, social dysfunction and severe depression [6]. The GHQ-28 focuses on breaks in normal function that lead to an inability to carry out one's normal healthy activities. The questionnaire is concerned with the manifestation of new phenomena of a distressing nature within the last few weeks [5].

The GHQ-28 was originally developed in English for Londoners. The questionnaire has been translated into several different languages, including a Norwegian translation by Tom Andersen [8]. The dimensions of psychological health have been suggested to be universal across cultures [6]. The stability of the factor structures has been evaluated [9, 10] across different cultures and samples [11–14]. The stability has mostly been confirmed across several different centres, except for that in the study of Prady et al. They did not confirm goodness of fit to the original structure or measure invariance across different cultures [12].

Two studies have assessed the validity of the GHQ-28 for screening for post-stroke depression, in relation to diagnosis by a standardized psychiatric interview [15, 16]. The researchers found that patients with depression scored significantly higher on the GHQ-28 than non-depressed stroke patients. The only study found, that evaluated measurement invariance of GHQ-28 in a stroke population is that of Munyonbwe et al. [17], who evaluated measurement invariance prior to merging two samples for analysis. In their conclusion, the researchers established a strong measurement invariance in two different stroke populations and confirmed the original four-factor structure. They did not assess the measurement invariance over time, but recommended that future research on measurement invariance also evaluate if the same construct is being measured across different time points within samples [17].

In Norway, psychometric properties of the GHQ-30 version have been examined when used in a population of older people living at home [18]. In this study, the original factor structure of the GHQ-30 was supported. Sveen et al. [19] tested the factor structure of the 20-item version in patients who had suffered a moderate stroke. The factor analysis in that study generated three factors: anxiety, coping, and satisfaction. The factor structure of the Norwegian version of GHQ-28 has not previously been examined when applied to a stroke population.

Finding the right outcome measurement is an important aim when evaluating a complex intervention [20]. Culture and treatment vary between populations and countries. We believe that an investigation of the GHQ-28 when applied in a Norwegian stroke population are a valuable contribution to the knowledge of suitable outcome measurements for evaluating effect of psychosocial interventions in various stroke populations.

The aim of the present study was to explore the psychometric properties of the GHQ-28 when applied in a Norwegian stroke population by evaluating the internal consistency, exploring the factor structure, construct validity and measurement invariance.

Methods

Setting and study population

In total, 353 patients from 11 Norwegian acute stroke or rehabilitation units providing acute stroke care were included in the study from November 2014 to November 2016. The inclusion criteria were as follows: the participants should be 18 years of age or older, have suffered an acute stroke within the last month, be medically stable, be evaluated by the recruiting personnel to have sufficient cognitive functioning to participate, be able to understand and speak Norwegian, and be capable of giving informed consent. Exclusion criteria were having moderate to severe dementia, other serious somatic or psychiatric diseases, or severe aphasia.

Data collection procedures

Data were collected at baseline (T1) and six (T2) months post-stroke. The GHQ-28, administered as a highly structured interview, was the primary outcome measurement of the RCT along with five secondary outcome measurements and the registration of demographic data. The data collection were conducted in the participants' homes or wherever the participants were at the time of the assessment. The assessor read the questions to the respondent, and recorded the respondent's answers in a web-based secure questionnaire by using a tablet.

GHQ-28

To evaluate the effect of the psychosocial intervention on well-being, the GHQ-28 was chosen as the primary outcome based on results from a comparable trial and because it was evaluated as an appropriate tool to capture emotional stress [5]. The GHQ-28 requests participants to indicate how their health in general has been over the past few weeks, using behavioural items with a 4-point scale indicating the following frequencies of experience: "not at all", "no more than usual", "rather more than usual" and "much more than usual". The scoring system applied in this study was the same as the original scoring system [6], the Likert scale 0, 1, 2, 3 [21]. The minimum score for the 28 version is 0, and the maximum is 84. Higher GHQ-28 scores indicate higher levels of distress. Goldberg suggests that participants with total scores of 23 or below should be classified as non-psychiatric, while participants with scores ≥ 24 may be classified as psychiatric, but this score is not an absolute cut-off. It is recommended that each researcher derive a cut-off score based on the mean of their respective sample [22].

Statistics

Exploratory factor analysis (EFA) was performed using SPSS Statistics for Windows, Version 24.0 [23]. Monte Carlo PCA was used for the parallel analysis [24]. The lavaan package version 0.5–23 [25] in R version 3.03 [26] was used to conduct the confirmatory factor analysis (CFA) and the analysis of metric invariance.

The minimum amount of data for factor analysis was satisfied [27, 28], with a final sample size of 322 (complete cases) for the exploratory factor analysis at time point T1 (providing a ratio of 11.5 cases per variable). The 285 complete cases with data from both T1 and T2 were used for the CFA (providing a ratio of 10.2 cases per variable).

The data were screened for outliers, skewness and missing values. The missing values were treated as missing at random (MAR). Using multiple imputation by chained equations (MICE) in SPSS, the single missing items where imputed at both time points [29, 30]. The MICE imputation model was constructed to include each of the 28 single items across time points both as predictors and to be imputed using the SPSS default imputation method of linear regression. Item constraints were limited according to the Likert-scoring method and imputation was specified to the closest integer. The multiple imputation produced five imputed data sets. Because we only use the T1 data for the EFA and exclude the cases completely missing at T2 for the CFA, missing values were minimal (< 1% for both time points). The result are therefore only presented from one (imputation 1) imputed dataset instead of pooled results of the five imputed datasets, which is an acceptable approach for very low proportions of missing data (< 3%) [31].

Initially, the factorability of the questionnaire was examined. Several criteria for the factorability of a correlation were used. The correlation matrix was examined for correlations above 0.3 [28]. The Kaiser-Meyer-Olkin (KMO) measure was used to test the sampling adequacy and was required to exceed 0.60 [32]. The result of Bartlett's test of sphericity [33] was considered statistically significant if the p-value was < 0.05. Cronbach's alpha was used to estimate the reliability of the instruments based on a required internal consistency > 0.7 [27, 34].

The factor structure was explored by EFA prior to evaluating construct validity by CFA. The EFA was conducted using the unweighted least squares method with direct oblimin rotation with Kaiser normalization to account for correlations between the items [28].

The number of factors to be retained was guided by three decision rules: Kaiser's criterion (eigenvalue > 1), inspection of the scree plots, and Horn's parallel analysis [24]. Parallel analysis has been shown to provide more consistent results when estimating the number of components than the more traditional methods based on eigenvalue > 1 and scree plots alone [27]. Only factors with eigenvalues that exceeded the corresponding values from the random dataset in the parallel analysis were retained. As recommended, only factors loading greater than 0.30 were displayed, making the output easier to interpret [27].

CFA, using maximum likelihood estimation was conducted to evaluate the model fit to the original construct of the GHQ-28 as proposed by Goldberg et.al [6], by examining if indicators of selected constructs loaded onto separate factors in the expected manner [35]. The analysis was performed by group using data from both the baseline and six-month datasets.

Several goodness-of-fit indicators were considered in the analyses. Comparative fit index (CFI) and Tucker-Lewis index (TLI) values less than .95 indicated lack of fit, and values above .95 indicated good fit [28, 36]. A root mean squared error of approximation (RMSEA) of .06 or lower is suggested to indicate a good fit [36].

We assessed measurement invariance by investigating three levels of invariance, as recommended in previous studies [37, 38]. The most basic level of measurement invariance is configural invariance, which assumes that the items load on the same latent factors across groups, but factor loadings can vary. The second level, metric invariance, requires that all factor loadings are the same across groups. Scalar invariance is the strongest form of invariance; it implies metric invariance and in addition tests if the intercepts are the same across the two time points. A change in CFI of less than 0.01 was considered evidence of invariance. This cut-off is based on the cut-off value used in a comparable study [17] and recommendations [36].

Results

Sample characteristics

The flow of participants is shown in Fig. 1 and the characteristics of the 322 randomized are shown in Table 1. The age ranged from 20 to 90 years, with a mean age of 66.2 years (SD 12.6). There were more males (59%) than females (41%) participating in the study. According to the measurement of neurological deficits, National Institutes of Health Stroke Scale (NIHSS), among the participants for whom we have information, 70% had no or minor symptoms (scoring between 0 and 5 on the NIHSS). In addition, based on the national register for stroke patients admitted to hospitals in Norway, our participants are on average 8 years younger than the national stroke population. We have 5% more men than expected based on the stroke population in Norway and fewer patients with higher stroke severity [39].

At 1 month post-stroke (T1), the sum scores on the GHQ-28 ranged from 6 to 72, with a mean sum score of 27 (SD 11.4). At 6 months post-stroke (T2), the sum scores ranged from 5 to 60, with a mean sum score of 20 (SD 10.2).

There were few missing values in the dataset, representing only 0.29% of the 11 total values for the single items at T1, and there were no complete missing cases. The total percentage of missing values at T2 was 11.6% measured in single items; however, after excluding the 37 complete missing cases, the percentage of missing values was only 0.09%.

The 37 participants that were lost to follow up at T2, did not have higher mean score on GHQ-28 compared to the 285 with data from both time points, but the mean age were higher (5 years) and they reported more severe symptoms, more depression and more experiences of fatigue. However, only data from participants that were assessed at both T1 and T2 was used for the CFA. Since we are comparing the same set of patients at T1 and T2, the results are comparable regardless of considering potential higher severity and consequences of stroke for the participants missing at T2.

Exploratory factor analysis (EFA)

No forced factors

The exploratory analysis of the imputed dataset, with no forced factors, resulted in five factors exceeding an eigenvalue of one, and the scree plot showed a change in the curve after five factors (Fig. 2).

Horn's parallel analysis (Table 2) showed that only four components exceeded the corresponding criterion value for a randomly generated data matrix of the same size (28 variables × 322 respondents).

Based on these analyses, four factors were retained for further EFA.

Four forced factors

Inspection of the correlation matrix revealed that all 28 items correlated > .3 with at least one other factor. There were significant positive correlations among the four latent factors (Table 3) supporting the use of oblique (oblimin) rotation [28] and indicating that respondents who showed high level in one dimension were more likely to show high level in the others as well.

The KMO measure was 0.883, and Bartlett's test of sphericity reached statistical significance ($p < 0.001$) supporting the suitability for factor analysis.

The rotated solution revealed a structure with a number of strong loadings > .45 [28]. Only five of the included variables loaded less than .45 (.34–.44). All the variables loaded substantially on one component.

The four-component solution explained a total of 51.6% of the variance at 1 month, with Factor 1 contributing to 27.8%, factor 2 contributing to 9.9%, factor 3 contributing to 8.2% and factor 4 contributing to 5.7%. Details from the analysis are listed in Table 4.

The Norwegian version of the GHQ-28 was internally consistent, as indicated by Cronbach alpha values of 0.844, 0.881, 0.838 and 0.719 for the four subscales.

Inspection of the pattern matrix shows that all the anxiety and insomnia questions cluster together, accompanied by one question from the social dysfunction subscale and three from the severe depression subscale. Only four questions remain in the severe depression factor. The questions regarding somatic symptoms cluster together with six of the questions from the social dysfunction subscale. The three questions concerning headaches or having hot or cold spells form their own category.

Overall, these results support a four-factor solution as proposed by Goldberg and Hillier [6]. However, the content of the factors does not fully support the original scale structure. This finding makes it difficult to confirm the original factor composition by examining the results

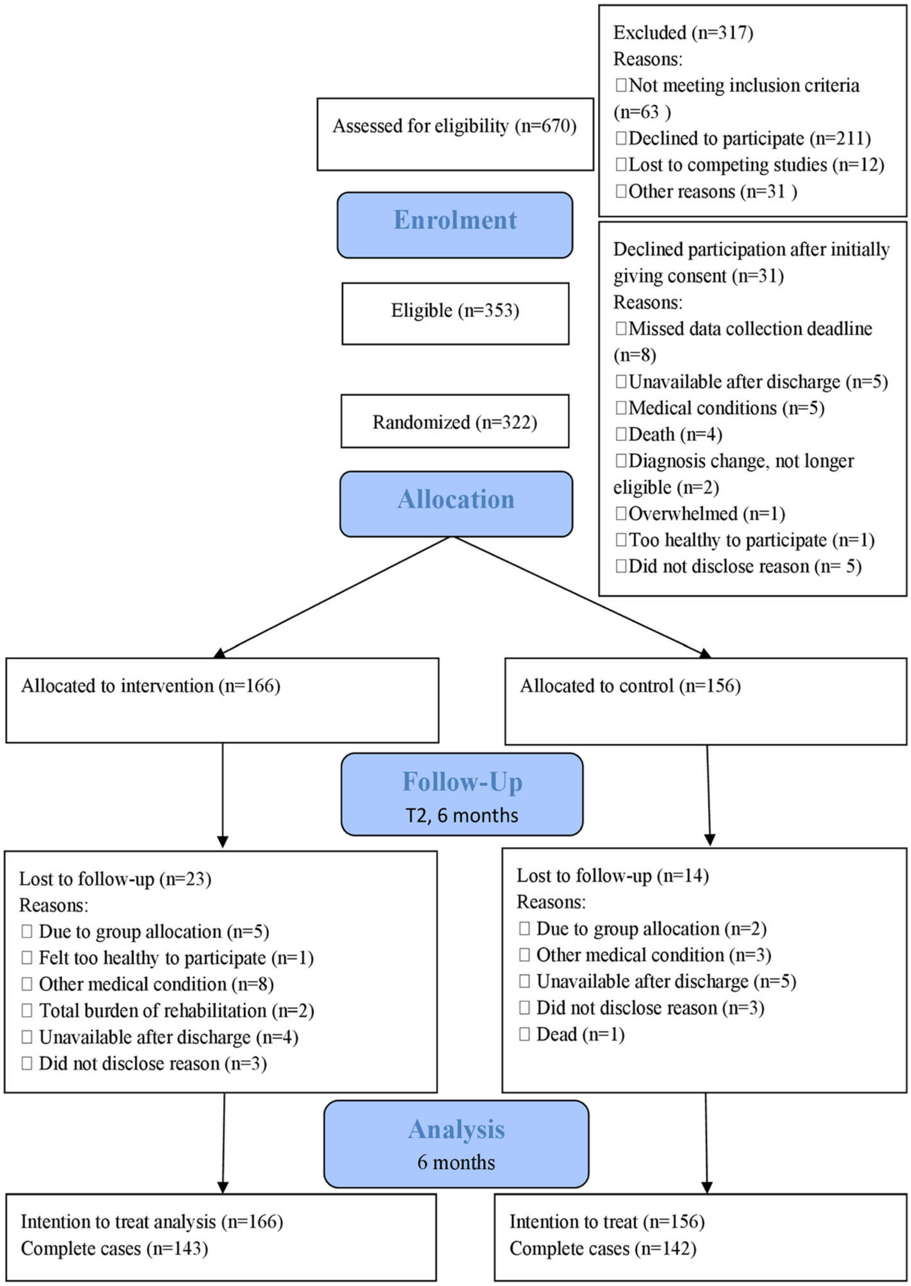

Fig. 1 CONSORT diagram of the flow of patients through the trial

of the EFA alone. Therefore, the next step taken was to test, by means of CFA, the fit of the original structure in our stroke sample.

Confirmatory factor analysis (CFA)

We fit the model using the full information maximum likelihood (FIML). The comparative fit indices (CFI and TLI) did not reach the level of 0.95, which would indicate a good fit [28, 36]. The root mean squared error of approximation (RMSEA), which assesses the extent to which a model fits reasonably well in a population [35], exceeded the recommended fit index of 0.06 by 0.02. By this, we could not confirm construct validity. The fit indices are listed in Table 5.

Measurements of invariance

The results from the testing of measurement invariance showed that the GHQ-28 questionnaire has comparable measurement properties at T1 and T2. The fit of the least restrictive configural invariance model was compared with

Table 1 Characteristics at baseline (T1) and data from the Norwegian stroke population

	Mean (SD)/ Total (%)	The Norwegian stroke register [a]
Age		
Mean (SD)	66.2 (12.6)	74.4
Median	67	76
Range	20–90	19–104
Missing	0	-
Gender		
Female	132 (41%)	3895 (46%)
Male	190 (59%)	4514(54%)
Missing	0	-
National Institutes of Health Stroke Scale (NIHSS) [b]		
0–5	170 (70%)	4119 (65%)
6–10	45 (19%)	1009 (16%)
11–15	17 (7%)	505 (8%)
16 +	8 (4%)	675 (11%)
Missing	82 (25%)	2230 (26%)
GHQ-28 sum score		
GHQ-28 (T1) Min 6, Max 72	27 (11.4)	-
Complete cases missing	0	-
GHQ-28 (T2 (*n* = 285)) Min 5, Max 60	20 (10.2)	-
Complete cases missing	37 (11%)	-

[a] Data from the Norwegian stroke population admitted to hospitals in 2015 registered in a Norwegian stroke register [39]. [b] Of the 240 patients for whom we had baseline data and the 6308 for whom data were registered in the Norwegian stroke register

the results from the more restrictive metric and scalar invariance models (Table 6). Neither the metric nor scalar invariance model produced a change in the CFI of ≥0.01, which confirmed the metric and scalar measurement invariance within groups for the two time points.

Discussion

The aim of the study was to explore the psychometric properties of the GHQ-28 when applied in a Norwegian stroke population by evaluating the internal consistency, exploring the factor structure, construct validity and measurement invariance.

Overall, the results from the EFA support a four-factor solution, but some of the items load on different factors from those in the original version proposed by Goldberg and Hillier [6]. The often-suggested threshold for the indices of goodness of fit in a CFA was not achieved, which indicates that caution is required when interpreting subfactor scores in a stroke sample. Measurement invariance was established for the same groups over two time points, which has, to the best of our knowledge, not previously been evaluated for GHQ-28 in a stroke population. This confirms that the same construct is being measured at both time points.

The EFA shows that the first factor in our sample addresses issues concerning anxiety and insomnia, in addition to one item from the social dysfunction subscale regarding enjoyment of daily activities and three items regarding nervousness and feelings of hopelessness originally categorized in the severe depression subcategory. This finding reflects the correlation between anxiety and depressive symptoms, which are known to be associated with one another in a stroke population [40, 41].

The second factor consists of the four most severe questions from the severe depression category about lack of joy in life and suicidality. The severity of the questions distinguishes them from the other questions regarding less severe depressive thoughts that correlate with anxiety and insomnia. Because the questions that address depressive thoughts are split between two factors in this study, examining the scoring in the original severe depression category alone is not sufficient when evaluating depression in a stroke population.

The third category contains four items from the original somatic symptoms factor and six items from the social dysfunction factor. Not feeling “perfectly well and in good health” in addition to feelings of being “run down and out of sorts”, “in need of a good tonic” or having “feelings of being ill” are, not unexpectedly, associated with social dysfunction. Altogether, these seven subjective evaluation questions address factors of social

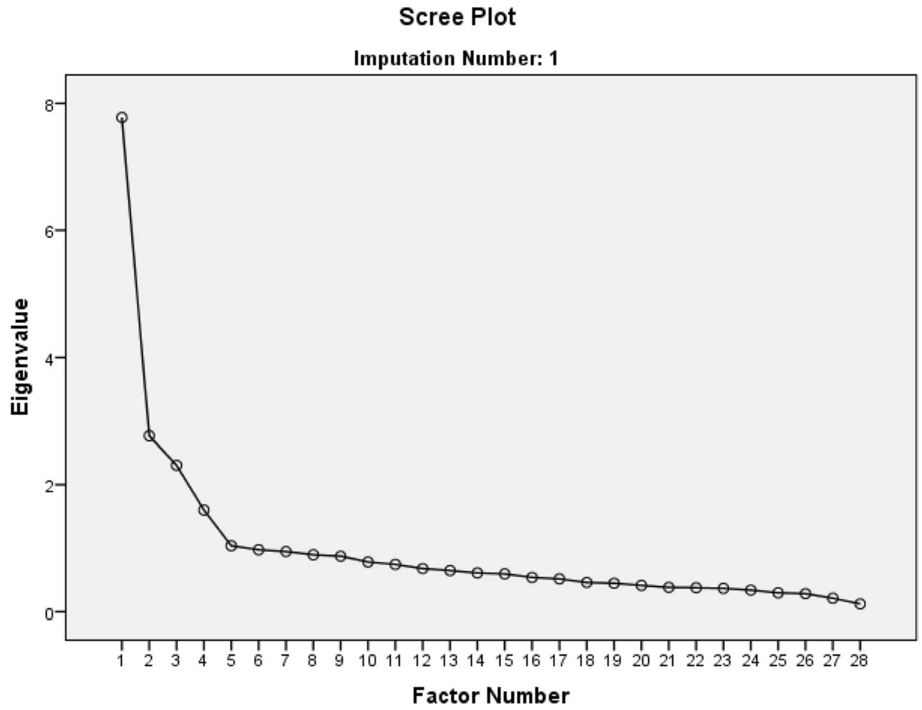

Fig. 2 Screeplot from the EFA with no forced factors

interrelation, emotional reactions, and judgements formed about life satisfaction and fulfilment, which can be interpreted as aspects of social function and psychosocial well-being.

The original population in which the measurement was developed did not suffer from any specific somatic illnesses. It has previously been claimed that certain responses on the GHQ-28 can be produced by physical or psychiatric disease [8, 42, 43]. In our study, an example of this situation is particularly apparent when we investigate the fourth factor from the EFA. This factor is formed by the items addressing somatic symptoms such as headache or having hot or cold spells. Pain and headache is a complication that can occur after stroke [44] and may also be a known side effect of medications used as secondary prevention after stroke [45] and is therefore not necessarily related to psychological distress. Even if an association with psychological challenges can be argued, forming a separate category, this does not necessarily make the items irrelevant to the evaluation of psychosocial well-being using the GHQ-28 total score since pain is known to be associated with health-related quality of life [46].

There are challenges applying a rating scale across countries and languages and to different populations. The stability of the factor structure has been examined in a study comparing the results from several different countries [10]. The researchers highlight some factors that might explain the differences as variances in the expression of distress, effect of translation and degree of industrial development. In our sample, most of the participants were born in Norway to Norwegian parents (92%). Even if the sample in this study is homogeneous, the original factor structure was developed in a London cultural setting. Subtle changes in understanding due to linguistic nuances or cultural differences in beliefs about

Table 2 Horn's parallel analysis of the five factors exceeding an eigenvalue of 1

Component number	Actual eigenvalue from the EFA at T1	Criterion value from the parallel analysis	Decision
1	7.795	1.589	Accept
2	2.772	1.497	Accept
3	2.302	1.433	Accept
4	1.596	1.381	Accept
5	1.038	1.331	Reject

Table 3 Factor correlation matrix [a]

Factor	1	2	3	4
1	1000	−0,380	−0,459	0,279
2	−0,380	1000	0,259	0,017
3	−0,459	0,254	1000	-0,157
4	0,279	0,017	-0,157	1000

Extraction Method: Unweighted Least Squares. Rotation Method: Oblimin with Kaiser Normalization, Imputation 1

[a] If correlations between factors are > 0.3, oblique rotation is the recommended approach because it produces a clearer result than orthogonal

Table 4 Exploratory factor analysis (EFA) with four forced factors (*n* = 322, Imputation 1)

	Factor 1 Explaining 27.8% of the variance Cronbach's α: 0.844		Factor 2 Explaining 9.9% of the variance Cronbach's α: 0.881		Factor 3 Explaining 8.2% of the variance Cronbach's α: 0.838		Factor 4 Explaining 5.7% of the variance Cronbach's α: 0.719		
	Pattern	Structure	Pattern	Structure	Pattern	Structure	Pattern	Structure	[a]
(A) Somatic symptoms									
1. Been feeling perfectly well and in good health?					−0.742	−0.694			0.457
2. Been feeling in need of a good tonic?					−0.364	−0.430			0.270
3. Been feeling run down and out of sorts?					−0.514	−0.569			0.378
4. Been feeling that you are ill?					−0.491	−0.568			0.432
5. Been getting any pains in your head?							0.718	0.754	0.535
6. Been getting a feeling of tightness or pressure in your head?							0.637	0.677	0.518
7. Been having hot or cold spells?							0.448	0.508	0.320
(B) Anxiety and insomnia									
1. Been losing much sleep over worry?	0.572	0.610							0.414
2. Been having difficulty in staying asleep once you fall asleep?	0.344	0.433							0.321
3. Been feeling constantly under strain?	0.585	0.585							0.372
4. Been getting edgy or bad tempered?	0.485	0.508							0.327
5. Been getting scared or panicky for no reason?	0.635	0.612							0.444
6. Been feeling everything is getting on top of you?	0.621	0.659							0.442
7. Been feeling nervous and strung-out all the time?	0.710	0.713							0.482
(C) Social dysfunction									
1. Been managing to keep yourself busy and occupied?					−0.521	−0.553			0. 381
2. Been taking longer over the things you do?					−0.670	−0.644			0.427
3. Been feeling on the whole that you were doing things well?					−0.692	−0.689			0.480
4. Been satisfied with the way you have carried out your tasks?					−0.688	−0.716			0.499
5. Been feeling that you are playing a useful part in things?					−0.646	−0.643			0.439
6. Been feeling capable of making decisions about things?					−0.349	−0.403			0.220
7. Been able to enjoy your normal day-to-day activities?	0.392	0.442							0.327
(D) Severe depression									
1. Been thinking of yourself as a worthless person?	0.515	0.589							0.469
2. Been feeling that life is entirely hopeless?	0.580	0.670							0.584
3. Been feeling that life is not worth living?			−0.591	−0.699					0.560
4. Been thinking of the possibility that you may do away with yourself?			−0.974	−0.957					0.827
5. Been feeling at times that you could not do anything because your nerves were too bad?	0.493	0.596							0.480
6. Been finding yourself wishing you were dead and away from it all?			−0.827	−0.856					0.730
7. Been finding that the idea of taking your own life keeps coming into your mind?			−0.869	−0.835					0.726

[a] Communalities indicate the amount of variance in each variable that is accounted for

Table 5 Fit indices and estimates of the latent variable for the T1 and T2 datasets (imputation 1) (n = 285)

Items	T1	T2
χ 2 (df)	p < 0.001 (378)	p < 0.001 (378)
CFI[b]	0.784	0.774
TLI	0.762	0.752
RMSEA	0.084	0.088
Latent variables[a]		
(A) Somatic symptoms		
Item 1	0.518	0.399
Item 2	0.452	0.457
Item 3	0.627	0.634
Item 4	0.702	0.535
Item 5	0.521	0.337
Item 6	0.501	0.475
Item 7	0.379	0.300
(B) Anxiety and insomnia		
Item 1	0.623	0.528
Item 2	0.390	0.416
Item 3	0.480	0.383
Item 4	0.442	0.449
Item 5	0.522	0.414
Item 6	0.570	0.499
Item 7	0.589	0.506
(C) Social dysfunction		
Item 1	0.449	0.406
Item 2	0.451	0.415
Item 3	0.413	0.365
Item 4	0.562	0.477
Item 5	0.453	0.414
Item 6	0.213	0.172
Item 7	0.333	0.269
(D) Severe depression		
Item 1	0.385	0.414
Item 2	0.436	0.480
Item 3	0.465	0.442
Item 4	0.410	0.347
Item 5	0.335	0.343
Item 6	0.413	0.456
Item 7	0.354	0.365

[a] All the estimates had a p-value < 0.001

[b] *CFI* comparative fit index, *TLI* Tucker–Lewis index, *RMSEA* root mean square error of approximation

Table 6 Overall fit indices from the measurement invariance tests

Measurement invariance model[a]	χ2(*df*)	CFI	TLI	RMSEA
Configural	2143.235 (688) p < 0.001	0.779	0.757	0.086
Metric	2176.377 (716) p < 0.001	0.778	0.766	0.085
Scalar	2262.083 (740) p < 0.001	0.769	0.764	0.085

[a] *CFI* comparable fit index, *TLI* Tucker-Lewis index, *RMSEA* root mean square error of approximation

health, expectations for the rehabilitation process or health care system may influence how the questionnaire was scored.

A strength in this study is that there were few missing items. Another strength is the application of both exploratory and confirmatory factor analyses.

One limitation is not having a sufficient sample to split the material for the EFA and CFA. Another limitation is that the patients with the most severe strokes or aphasia were difficult to enrol due to early inclusion and requirements for informed consent. Nevertheless, the study sample is representative of a large amount of the stroke population in Norway, since mild and moderate strokes are far more common than severe strokes [39].

Conclusions

The Norwegian version of the GHQ-28 confirms a four-factor solution, but with some differences in the factor structure compared to that of the original version. The CFA did not reach the strict cut-off for goodness of fit recommended in the literature. Measurement invariance across time points was confirmed, indicating that the same construct of the GHQ-28 is measured across time. However, the change in mean score on the GHQ-28 and the factor composition are assumed to be affected by characteristics in the stroke population. The results, when applying GHQ-28 in a stroke population, and sub-factor analysis based on the original factor structure should be interpreted with caution.

Abbreviations

CFA: Confirmatory factor analysis; CFI : Comparative fit index; EFA: Exploratory factor analysis; GHQ - 28: General Health Questionnaire - 28; KMO: Kaiser-Meyer-Olkin; NIHSS: National Institutes of Health Stroke Scale; RMSEA : Root mean square error of approximation; TLI : Tucker–Lewis index

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Availability of data and materials

Datasets generated and analyzed during the current study are not publicly available due to strict ethics regulation in Norway, but may be available from the corresponding author on reasonable request.

Authors' contribution

All authors have made substantial contributions to the manuscript and made the final approval of the version to be submitted. Even if EGH has been in charge of the process, the writing of the manuscript was done in close collaboration between all authors. EGH and MZ conducted the statistical analyses and MZ, LKB, MK, BT and US have reviewed and provided comments on the subsequent drafts.

Ethics approval and consent to participate

Ethical approval was obtained from the Regional Committee for Ethics in Medical Research (2013/2047) and by the Data Protection Authorities (2014/1026). All patients gave their written consent before inclusion.

Competing interests

The authors declare that they have no competing interests.

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ORIGINAL REPORT

EFFECT OF A DIALOGUE-BASED INTERVENTION ON PSYCHOSOCIAL WELL-BEING 6 MONTHS AFTER STROKE IN NORWAY: A RANDOMIZED CONTROLLED TRIAL

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Objective: **To evaluate the effect of a dialogue-based intervention on psychosocial well-being 6 months after stroke.**

Design: **Multicentre, prospective, randomized controlled trial.**

Subjects: **Adults (aged ≥18 years) who had their first or recurrent stroke within the last month, were medically stable, had sufficient cognitive functioning to participate and understood and spoke Norwegian.**

Methods: **A total of 322 participants were randomly assigned to the intervention ($n=166$) or control ($n=156$) group. Participants in the intervention group received up to 8 individual sessions aimed at supporting the coping and life skills of stroke survivors in addition to usual care. The primary outcome was the proportion of participants with normal mood measured by the General Health Questionnaire-28 (GHQ-28). The secondary outcomes included health-related quality of life (Stroke and Aphasia Quality of Life Scale; SAQOL-39g), depression (Yale-Brown single-item questionnaire; Yale) and sense of coherence (SOC-13).**

Results: **After controlling for the baseline values, no significant benefit was found in the intervention group over the control group (odds ratio (OR): 0.898: 95% confidence interval (95% CI): 0.54-1.50, $p=0.680$) 6 months post-stroke.**

Conclusion: **Psychosocial well-being improved during the first 6 months after stroke in both arms of the trial, but no statistically significant benefit of the dialogue-based intervention was found compared with usual care.**

Key words: psychosocial rehabilitation; stroke; intervention study; mood; psychosocial factor.

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LAY ABSTRACT

The aim of this study was to evaluate the effect of a dialogue-based intervention on psychosocial well-being 6 months after stroke. A total of 322 participants were assigned to an intervention ($n=166$) or control ($n=156$) group. Participants in the intervention group received up to 8 individual sessions aimed at supporting the coping and life skills of stroke survivors in addition to usual care. Psychosocial well-being improved during the first 6 months after the stroke in both arms of the trial. However, no benefit of the dialogue-based intervention was found compared with usual care.

Stroke is a major cause of death and disability globally and imposes social and economic burdens on individuals, families and communities (1). Every year, approximately 12,000 people suffer from stroke in Norway (2). Psychosocial challenges and emotional symptoms are frequent sequelae after stroke. Approximately one-third of patients report depressive symptoms (3) or anxiety (4) the first year post-stroke. Other common challenges include general psychological distress and social isolation (5). Psychosocial problems affect long-term functioning and health-related quality of life as well as motivation to participate in rehabilitation, but follow-up targeting psychosocial adjustment may improve psychosocial well-being, independent of functional impairment after stroke (6). To promote well-being, prevent additional negative consequences after stroke, and maximize the effect of rehabilitation, psychosocial well-being should be a focus during post-stroke care.

Systematic reviews have explored psychosocial interventions after stroke (3, 7–10). Although motivational interviewing is the only intervention with a documented effect (7), providing information (10), counselling (9) and liaisons with services (8) may contribute to psychosocial well-being. A study on motivational interviewing found a statistically significant benefit over usual stroke care. The results suggested that motivational interviewing led to improvements in the patients' mood 3 months after stroke, and the benefit was confirmed at 12 months (11).

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However, few dialogue-based psychosocial interventions to support stroke survivors' coping and life skills have been conducted by primary healthcare professionals in the municipalities. In Norway, implementation of the Coordination Reform in 2012 (12) resulted in a shift in focus from primarily treating patients in hospitals to a focus on prevention, improving coordination between different care levels, integrating care in the community, and strengthening healthcare in the municipalities. The overriding aim of the reform was to direct more investment towards primary care in order to curb increasing hospital expenditure. As part of this shift, providing rehabilitation near patients' homes in the municipalities was encouraged.

The dialogue-based intervention was developed and feasibility tested in accordance with the United Kingdom Medical Research Council (UK MRC) guidance on developing and evaluating complex interventions (13, 14). The intervention was found to be feasible to conduct in the municipalities, was tailored for stroke survivors and designed to be delivered in the early rehabilitation phase starting 4–6 weeks after stroke onset (15). A guiding topical outline and worksheets were developed to support the dialogues. The topics included emotions, social relationships, bodily changes, dynamic problem-solving, daily activities and identity (14, 15).

The theoretical perspectives underpinning the intervention included Antonovsky's (16) theory on salutogenesis, sense of coherence (SOC), narrative theory (17) and ideas from guided self-determination (18).

Based on the theoretical foundation and feasibility work, we hypothesized that support during the early adjustment phase following a stroke could lead to improvements in mood, reduced depression, enhanced health-related quality of life and improved understanding, manageability and meaning in their lives after stroke (14, 15).

The present study evaluated the effect of a dialogue-based intervention in addition to usual care on psychosocial well-being 6 months after stroke.

MATERIALS AND METHODS

Trial design and participants

This study was a multicentre, prospective, randomized controlled trial (RCT). Participants were recruited from 11 acute stroke or rehabilitation units in eastern Norway between November 2014 and November 2016.

Patients who met these criteria were invited to participate: aged ≥18 years and had had an acute stroke within the past month, were medically stable, had sufficient cognitive functioning to provide informed consent and participate, and understood and spoke Norwegian. Exclusion criteria were: severe dementia, other serious somatic or psychiatric diseases or severe aphasia. Recruiting personnel assessed the cognitive function and aphasia, which were discussed with the rehabilitation team at the recruiting institutions.

Interventions

All participants received usual care. Usual care included acute treatment at stroke units and rehabilitation centres or in the municipality. All participants were followed up by their physicians in accordance with the Norwegian clinical guidelines for treatment and rehabilitation after stroke (19) in addition to nursing and therapy input (e.g. through a multidisciplinary team) based on need and availability.

The dialogue-based intervention consisted of 8 individual sessions involving the participant and a registered nurse (RN) or occupational therapist (OT) recruited via the recruiting institutions, other stroke rehabilitation units or the community healthcare. All intervention personnel (IP) were required to complete a 3-day training programme. Group seminars led by members of the research team were arranged for the IP during the study. The seminars were an arena for guidance and supervision and allowed the research team to reinforce IP training and compliance to protocol in order to promote intervention fidelity.

The same RN/OT worked with the participant through all sessions. Interventions were delivered mainly in the participants' homes. The first of the 8 sessions began shortly after randomization (4–8 weeks post-stroke), and the final session was completed within 6 months. The number of sessions was chosen to balance the ideal with the realistic (i.e. as few encounters as possible, but enough to provide adequate support).

The sessions` content addressed feelings, thoughts and reflections related to the patients' experiences after stroke, and were based on topics highlighted as significant issues in the stroke literature and in the development and feasibility studies (14, 15).

Theoretically, experiences of chaos and a lack of control were perceived as potential threats to well-being following stroke. It was assumed that sense of coherence (SOC) could be promoted by experiencing diverse life events as comprehensible, manageable and meaningful. To promote SOC, the participants were encouraged to relate their experiences. Narrative theories emphasize that human beings create meaning in their lives through telling stories. By guided self-determination, the intervention sought to empower the participants to make decisions on issues related to well-being based on their values and perspectives (14).

More details on the topics of the dialogue-based sessions are provided in the Table SI and Table SII[1]. Further details regarding the development and adjustments of the intervention were provided in previous research (15).

Outcomes

The stroke aetiology, side localization of the stroke symptoms, cognitive function, and language difficulties were recorded at baseline after obtaining informed consent. Neurological deficits were evaluated using the National Institutes of Health Stroke Scale (NIHSS) upon admittance to the hospitals (20). Information regarding cognitive function (Mini Mental Status Evaluation; MMSE) was collected from the participant's medical record.

Participants were assessed prior to randomization using structured outcome measures 1 month post-stroke (T1). In addition, the data collector recorded the patient's age, sex, living situation,

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[1] http://www.medicaljournals.se/jrm/content/?doi=10.2340/16501977-2585

education, work status, caring responsibilities, social support, previous illnesses and rehabilitation services. Data collectors with healthcare backgrounds (RN or OT) administered the instruments using a personal interview format. The assessors read the questions to the respondent and recorded the respondent's answers in a web-based secure questionnaire using a tablet. At 6 months post-stroke (T2), a data collector who was blinded to the group allocation repeated the outcome measurements. Any changes in the patient's living situation or health status since the first assessment were recorded.

The term psychosocial refers to the interrelation between social factors and individual thoughts and behaviours. Well-being generally refers to emotional reactions and subjective evaluations in response to events and includes a greater prevalence of positive than negative emotions and moods, satisfaction with life, sense of fulfilment, and positive relationships (21, 22). The primary outcome to evaluate psychosocial well-being was the General Health Questionnaire-28 (GHQ-28) (23). The GHQ-28 has been translated into Norwegian (24) and evaluated as an appropriate tool for research purposes in studies to capture emotional stress (25). The GHQ-28 consists of the following 4 subscales addressing aspects of psychosocial well-being: somatic symptoms, anxiety and insomnia, social dysfunction and severe depression (23). Higher score on the GHQ-28 indicates higher distress levels. The continuous GHQ-28 score was calculated based on a Likert scoring of 0, 1, 2, 3, resulting in a scale of 0–84. The dichotomized GHQ-28 score was based on a case scoring of 0, 0, 1, 1, resulting in a scale of 0–28. Based on a comparable study (11) the cut-off was set at 5 in the dichotomized GHQ-28 variable. Scores <5 indicated a normal mood, and scores ≥5 indicated a low mood.

Three secondary outcomes were explored. The Yale-Brown single-item questionnaire (Yale) measures the individual's presence or absence of depression (26). The Stroke and Aphasia Quality of Life Scale-39 (SAQOL-39g) addresses dimensions of stroke-specific health-related quality of life and is adjusted for people with aphasia (27). SAQOL-39g items are scored on a scale from 1 to 5, and mean scores are calculated for each dimension and for the total sum score. Higher scores indicate a higher quality of life. The SOC-13 measures the main concepts of SOC theory (16). In this study, the SOC-13 items were scored on a scale from 1 to 5. The total sum score was calculated after reversing the scores of the reversely formulated items, resulting in a scale from 13–65. Higher scores indicate higher levels of comprehensibility, manageability, and experiences of meaningfulness in life.

The fatigue questionnaire (FQ-2), Lee's fatigue scale (LFS-5) (28) and the Ullevaal Aphasia Screening test (UAS) (29) were included to describe the sample.

Sample size calculations

Sample size was determined based on the primary outcome measurement. With the power set at 80% and the significance level (α) at 0.05, the estimated sample size was 300 patients (150 per group). The calculations were based on a repeated measures logistic regression model of the output variable "normal mood" (GHQ-28). In this study, the power of finding a statistically significant difference between groups was 80% for an OR of 1.9 or higher.

Randomization and blinding

A computer-generated block randomization procedure was used to allocate the patients into either the intervention or control arm. Participants were randomly assigned in blocks of 10, stratified by the recruiting centre with an allocation ratio of 5:5. An assistant independent of the research group prepared opaque randomization envelopes with 5-digit patient identification numbers printed on the outside and a note specifying intervention or control on the inside. Two regional study coordinators performed the randomization. Group allocations were communicated solely to the patient and the IP delivering the intervention. To maintain blinding during follow-up, a text message was sent from the study coordinator to the participants before the data collector contacted them with a reminder not to reveal their group allocation.

Statistical methods

The data were analysed using the Statistical Package for the Social Sciences (SPSS), version 25.0, for Windows (IBM Corp., Armonk, NY, USA). All statistical tests were intention-to-treat analyses performed as 2-sided tests with a significance level of α=0.05. Missing data were imputed using multiple imputation by chained equations (MICE) in SPSS (30), and all reported results from the statistical analyses were combined results across 5 imputations based on Rubin's rule (31).

A logistic regression with time points (T1 vs T2) as the single independent variable was used to assess the odds of a normal mood (GHQ-28<5) and not having depression (Yale) from T1 to T2 separately per treatment group. The changes in mean scores on the SAQOL-39g and SOC-13 from T1 to T2 were examined for each treatment group using paired-sample *t*-tests.

Logistic regression analyses were used to analyse the effects of the intervention on mood (GHQ-28) and depression (Yale) at 6 months. Multiple linear regression analysis was applied to determine whether participating in the intervention was statistically significantly associated with the participants' scores on the SAQOL-39g. Based on conceptual and theoretical assumptions, the following baseline characteristics were controlled for in the regression models in each analysis: group allocation, sex, age at admission, rehabilitation services at baseline, care responsibility, living arrangements, comorbidity, stroke severity (NIHSS), stroke aetiology, stroke symptom localization, depression, fatigue and SOC (SOC-13). The baseline value of the outcome measurement analysed was also added as a covariate because the results of the by-group analyses showed significant changes between time points. A variable of recruitment centre was in addition included in the logistic regression analysis of GHQ-28 to control for a potential effect of recruitment centre.

The SAQOL-39g was analysed for both the original and log-transformed (2**) variables because of the non-normal distribution of the data. The results were compared, and no significant differences were found. To simplify interpreting the results, only outcomes from the original data analysis are presented herein.

Independent-samples *t*-tests were used to test for statistically significant differences in the mean scores on the SOC-13 between the intervention and control groups.

Ethics

The ethical approval of the study was provided by the Regional Committee for Ethics in Medical Research (REC) (2013/2047) and the Data Protection Authorities (2014/1026). The study followed the guidelines of the Declaration of Helsinki.

When invited to participate, eligible participants received oral and written information about the study from trained clinical staff who also obtained informed consent.

If patients showed signs of severe emotional distress during the interviews or intervention, the interviewer/intervention personnel were instructed to offer to interrupt the interview or intervention and consider contacting their general practitioner, a family member or home-care services.

RESULTS

A total of 670 stroke patients were assessed for eligibility, of whom, 353 consented to participate. A final total of 322 participants were randomly assigned to the intervention ($n = 166$) or control ($n = 156$) group. The REC only gave permission to register information on the sex and age of the participants who declined to participate. Unfortunately, not all recruiting centres provided complete data; however, in the largest recruiting centre the mean age of those who consented were 64.1 years compared with 64.4 years in the group who did not consent ($p = 0.893$). The proportion of men and women who consented, 60.8% and 39.2%, respectively, compared with 58.2% and 41.8% who did not consent ($p = 0.679$) shows no sex disproportion in the groups.Thirty-one participants declined after initially giving consent, reasons are listed in the flow diagram (Fig. 1). Twenty-three participants (7.1%) in the intervention group and 14 (4.4%) in the control group were lost to follow-up at 6 months. Consequently, 285 participants (88.5%) completed the follow-up assessments at 6 months. Fig. 1 shows the participant flow diagram.

Baseline characteristics were generally well balanced between the groups (Table I). A numerical difference was noted for depression (Yale), on which 17.5% of participants in the intervention group and 27.6% of those in the control group reported depression at T1. The participants' mean age was 8 years younger than that of the average stroke patients admitted to hospitals in Norway; 5% more were men, and more patients scored ≤5 on the NIHSS upon hospital admission (70% vs 65%) (2).

Analysis of the implementation fidelity showed that the intervention's core components were delivered according to protocol, although the intervention trajectories were individualized (32). Based on a composite score of the adherence measures (number of sessions, timeliness of starting, and duration of intervention), 80% of the intervention programmes were implemented with high fidelity. This means that

Table I. Sample characteristics of the stroke study sample ($n = 322$) at baseline

Variable	Intervention group ($n = 166$)	Control group ($n = 156$)
Demographics and psychosocial factors		
Age, years, mean (SD)	66 (12.1)	65 (13.3)
Female sex, *n* (%)	67 (40.4)	65 (41.7)
Living with someone, *n* (%)	117 (70.5)	101 (63.7)
Education ≥ college/university degree ($n = 165$; 155), *n* (%)	51 (30.8)	52 (33.3)
Working prior to stroke ($n = 165$; 156), *n* (%)	64 (38.6)	57 (36.5)
Receiving rehabilitation services, *n* (%)	114 (68.7)	99 (63.5)
No caring responsibility, *n* (%)	129 (77.7)	120 (76.9)
Having social support, *n* (%)	154 (98.8)	152 (97.4)
Clinical characteristics		
Stroke aetiology ($n = 147$; 144), *n* (%)		
Ischaemic infarction	128 (87.1)	136 (94.4)
Haemorrhage	19 (12.9)	8 (5.6)
Stroke symptom localization ($n = 164$; 151), *n* (%)		
Right	65 (45.8)	56 (41.2)
Left	70 (49.3)	74 (54.4)
Bilateral	7 (4.9)	6 (4.4)
NIHSS, ($n = 126$; 114), median (IQR)	4.0 (1.0–7.0)	2.5 (1.0–6.0)
0–5	85 (67.5)	85 (74.6)
6–10	28 (22.2)	17 (14.9)
11+	13 (10.3)	12 (10.5)
No comorbidity, *n* (%)	31 (18.7)	32 (20.5)
UAS, ($n = 163$; 156), median (IQR)	52 (50–52)	52 (50–52)
MMSE, ($n = 63$; 65), median (IQR)	27 (25–29)	28 (26–30)
Outcome measurements		
Normal mood (GHQ-28<5) ($n = 160$; 151), *n* (%)	50 (30.0)	46 (29.0)
Stroke and Aphasia Quality of Life Scale (SAQOL-39g) ($n = 154$; 143) (Scale: 1–5), median (IQR)	4.35 (3.7–4.5)	4.25 (3.7–4.6)
Physical domain	4.62 (4.0–4.9)	4.53 (3.9–4.8)
Communication domain	5.00 (4.8–5.0)	5.00 (4.8–5.0)
Psychosocial domain	3.93 (3.3–4.5)	3.84 (3.2–4.3)
Feeling sad or depressed (Yale), *n* (%)	29 (17.5)	43 (27.6)
Sense of coherence (SOC-13) (Scale: 13–65), ($n = 165$; 156), mean (SD)	50.6 (5.4)	50.4 (5.8)
Feeling fatigued (FQ-1), ($n = 165$; 156), mean (SD)	88 (53.3)	87 (55.8)
Lee's fatigue scale (Lee 5): (Scale: 1–10), ($n = 164$; 156), mean (SD)	3.47 (1.8)	3.58 (1.9)

SD: standard deviation; IQR: interquartile range; NIHSS: National Institutes of Health Stroke Scale; MMSE: Mini Mental Status Examination; UAS: Ullevaal Aphasia Screening.

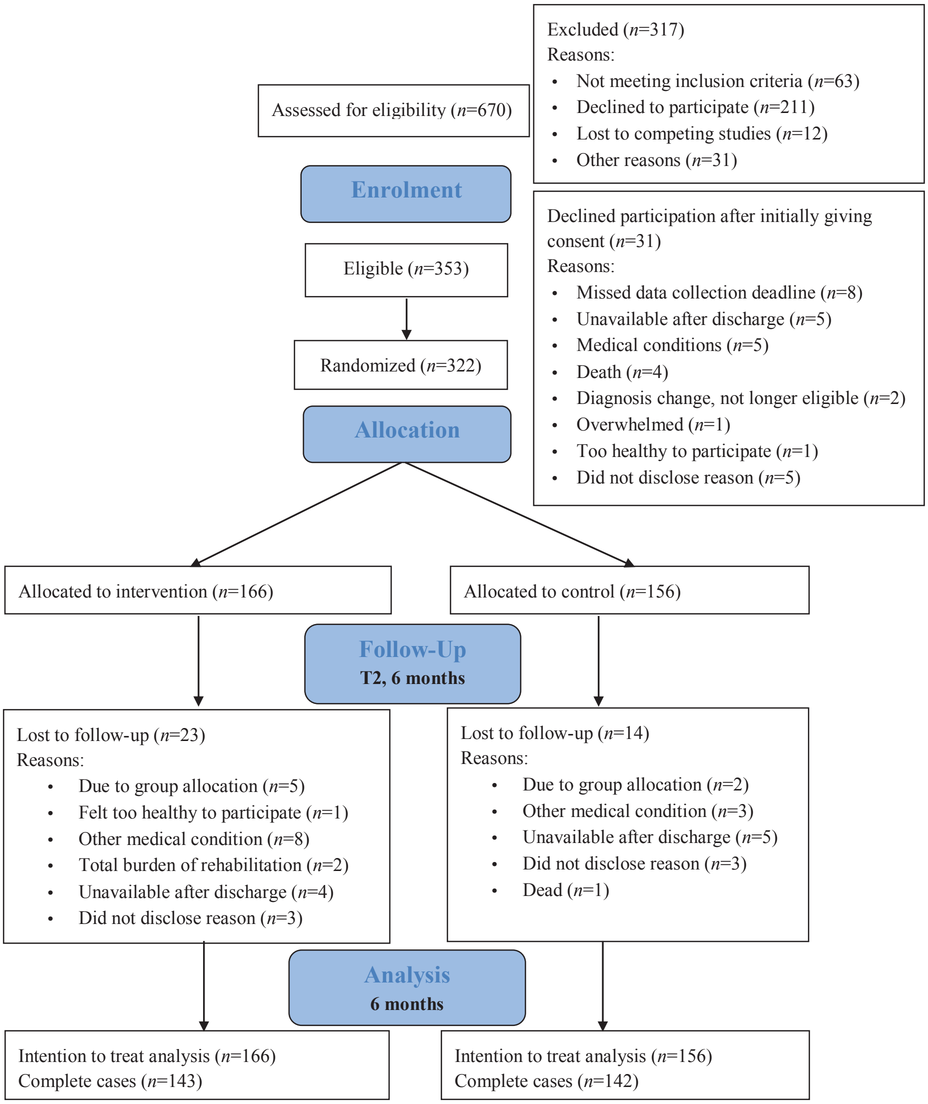

Fig. 1. Flow chart of the study.

the intervention trajectory was complete (≥6intervention sessions); it began between 4 and 8 weeks (mean 49 days ($n=147$)) after the stroke, and the frequency and total duration were a maximum of 17 weeks from session 1 to session 8.

Primary outcome

After dichotomizing the sum score, 99 of the 166 patients (59.6%) in the intervention group and 93 of the 156 patients (59.6%) in the control group had normal mood (GHQ-28<5) at 6 months. Table II shows that, compared with that at baseline, the proportion of participants with normal mood increased in both the intervention and control groups.

After controlling for the baseline characteristics and recruitment centre, in the logistic regression model, no benefit of the dialogue-based intervention was observed over usual care on mood at T2 (OR: 0.898: 95% CI: 0.54–1.50, $p=0.680$) .

By separately exploring the results for the intervention and control groups, it was found that no baseline characteristics demonstrated statistically significant effects on mood at T2 in the intervention group. Two baseline factors affected the odds of a normal mood at T2 in the control group. Higher SOC (OR: 1.098, 95% CI: 1.01–1.19, $p=0.026$) increased the odds of normal mood, while comorbidities (OR: 0.282, 95% CI: 0.09–0.83, $p=0.022$) decreased the odds of normal mood. This difference should be further explored when the 12-month data are available.

Secondary outcomes

Thirty-seven participants (22.3%) in the intervention group and 36 (23.1%) in the control group reported depression at 6 months (Yale). Compared with those at T1, the intervention group had 8 more participants (4.9%) who reported depression, while the control group had 7 fewer participants (5.4%) who reported depression.

After controlling for the baseline characteristics, the logistic regression model for depression (Yale) showed no benefit of the intervention over usual care at T2 (OR: 1.248, 95% CI: 0.64–2.41, $p=0.507$).

By separately exploring the results for the intervention and control groups, it was found that depression at T1 statistically significantly increased the odds of depression at T2 for both the intervention (OR: 5.054 95% CI: 1.73–14.74, $p=0.003$) and the control group (OR: 8.965 95% CI: 2.79–28.72, $p=0.001$) at 6 months.

Table II shows that the physical domain score on the SAQOL-39g changed significantly from T1 to T2 for both the intervention and control groups.

After controlling for the baseline characteristics in the multiple linear regression model, the analysis showed no benefit favouring the intervention over usual care on the SAQOL-39g mean score (B=–0.026, CI: –0.13–0.08, $p=0.637$) at 6 months. Table II lists the subdomain statistics.

When the intervention and control group results were explored separately, it was found that the T1 SAQOL-39g score was a predictor of the T2 SAQOL-39g score in both the intervention (B=0.380, CI: 0.08–0.67, $p=0.015$) and control group (B=0.464, CI: 0.29–0.63, $p<0.001$) at T2. For the intervention group, the NIHSS scoring predicted the T2 SAQOL-39g score (B=–0.030, CI: –0.51 ao –0.01, $p<0.004$) and for the control group, the SOC-13 (B=0.013, CI: 0.01–0.02, $p<0.034$) predicted the SAQOL-39g score.

Table II shows that the mean sum score on the SOC-13 did not change significantly from T1 to T2 in the intervention or control group, and that the between-group difference at 6 months was not statistically significant.

DISCUSSION

Main findings

Compared with baseline, the proportion of participants reporting normal mood statistically significantly increased in both the intervention and control groups at 6 months. In contrast to our hypothesis, this study failed to demonstrate that a dialogue-based intervention promoted psychosocial well-being in the intervention group compared with the control group.

Table II. Effect of intervention on outcomes 6 months after stroke

	Intervention $n=166$				Control $n=156$				Between-group differences	
Variable[a]	T1	T2		p-value	T1	T2		p-value		p-value
Primary outcomes										
Normal mood (GHQ-28≤5), n (%)[b]	50 (30.1)	99 (59.6)	3.392 (2.12 to 5.42)[c]	<0.001	46 (29.5)	93 (59.6)	3.528 (2.18 to 5.70)[c]	<0.001	0.898 (0.54 to 1.50)[c]	0.680
GHQ-28, mean (SE)	25.9 (0.84)	21.2 (0.83)	4.762 (2.90 to 6.62)	<0.001	28.5 (0.89)	21.5 (0.89)	6.979 (5.16 to 8.79)[d]	<0.001	0.302 (−1.99 to 2.60)[e]	0.797
Secondary outcomes										
Depressed (Yale), n (%)[b]	29 (17.4)	37 (22.3)	1.343 (0.75 to 2.39)[c]	0.318	43 (27.6)	36 (23.1)	0.776 (0.46 to 1.32)[c]	0.349	1.248 (0.64 to 2.41)[c]	0.507
Quality of Life (SAQOL-39g), mean (SE)[f]	4.30 (0.04)	4.38 (0.05)	−0.085 (−0.18 to 0.01)[d]	0.080	4.24 (0.05)	4.37 (0.04)	−0.128 (−0.21 to −0.46)[d]	0.003	−0.026 (−0.13 to 0.08)[g]	0.637
Physical domain	4.24 (0.07)	4.52 (0.06)	−0.281 (−0.42 to −0.14)[d]	<0.001	4.21 (0.08)	4.52 (0.05)	−0.313 (−0.45 to −0.17)[d]	<0.001	−0.028 (−0.14 to 0.09)[g]	0.645
Communication domain	4.75 (0.04)	4.76 (0.03)	−0.012 (−0.87 to 0.62)[d]	0.742	4.74 (0.05)	4.79 (0.03)	−0.045 (−0.12 to 0.33)[d]	0.263	−0.031 (−0.10 to 0.04)[g]	0.437
Psychosocial domain	3.90 (0.06)	3.86 (0.07)	0.037 (−0.11 to 0.19)[d]	0.626	3.76 (0.06)	3.79 (0.07)	−0.027 (−0.16 to 0.10)[d]	0.691	−0.004 (−0.21 to 0.20)[g]	0.967
Sense of coherence (SOC) Mean (SE)	50.6 (0.42)	50.2 (0.58)	0.391 (−0.72 to 1.50)[d]	0.489	50.4 (0.46)	50.5 (0.52)	−1.112 (−1.05 to 0.82)[d]	0.814	0.276 (−1.27 to 1.82)[e]	0.726

[a] Reporting pooled results of imputed data.

[b] Full logistic regression models are provided in the supplementary material.

[c] Logistic regression (OR [95% CI]),

[d] Paired-sample *t*-test (Mean difference [95% CI]),

[e] Independent sample *t*-test (Mean difference [95% CI]).

[f] Multiple regression models are provided in the Table SI and Table SII.

[g] Reporting adjusted difference in means from a multiple linear regression model, B (95% CI).

No change was detected in the SOC after the intervention. However, the results indicated that a higher SOC level might have a protective effect against the potentially stressful situation imposed by a stroke. The SOC is considered to be strongly related to perceived health (16). Despite the adverse health experiences after a stroke, participants with higher SOC scores had higher odds of a normal mood and higher scores regarding health-related quality of life at T2. This result is consistent with Antonovsky's (16) theory on salutogenesis, which explains how some people manage well despite adverse health experiences. This finding is also supported by a recent study on how personal factors, such as proactive coping, influence stroke outcomes, seem to be stable over time (33) and demonstrated that in the period from 2 months to 2 years after stroke personal factors did not improve naturally.

Our results differed from those reported in a comparable study that evaluated the effect of motivational interviewing on mood (11). Watkins and colleagues reported a significant difference between the intervention and control groups at 3 months, with 49% of the participants in the intervention group and 39% of the participants in the control group having normal mood at 3 months. At 12 months, the difference between the groups remained significant, with 48% of participants in the intervention group and 37% of participants in the control group reporting normal mood. Watkins' study was conducted in a hospital with a different and shorter intervention, and the data were primarily collected by mail. Comparably, a substantially higher percentage of participants in both groups (59.6%) had normal mood at 6 months in our study. Although the results failed to demonstrate effectiveness of this dialogue-based intervention for promoting psychosocial well-being after stroke, conducting an RCT in a complex setting with face-to-face data collection imposes several factors that may explain the neutral results obtained in this study.

The Norwegian authorities have encouraged rehabilitation services delivered in the municipalities through the Coordination Reform (12) and through the clinical guidelines for treatment and rehabilitation after stroke (19). A considerable proportion of participants reported receiving rehabilitation services post-stroke (66% at T1 and 55% of T2). Therefore, the rehabilitation needs of some participants may have already been met through usual care. No standardized psychological support exists in the follow-up after stroke in Norway and we lack a complete overview of the content of the follow-up that the participants received. However, since the participants lived in more than 70 different municipalities, we must assume that the follow-up varied substantially.

The most frequently reported follow-up was physical therapy (59% at T1, 36% of T2). This finding was supported by a recently conducted study comparing stroke rehabilitation in Norway and Denmark, suggesting that follow-up focuses more on physical rehabilitation in Norway, while psychological support is better organized and implemented in Denmark (34).

We experienced that some of the participants struggled to distinguish ordinary healthcare services from the intervention, and participants in the control group perceived the study participation and the structured assessment interviews as a form of intervention. Conducting face-to-face assessments ensured high compliance and complete data during collection, but also had some disadvantages. Face-to-face interviewing is a form of social interaction and merely being involved in these interviews may have positively affected the patients' psychosocial well-being. Having an interviewer visit their homes 1 and 6 months after discharge may have also led to the perception of having received an intervention, even by those in the control group.

Social desirability bias (35) is another factor that potentially affected the results. If the respondents had acted in ways or held attitudes that they felt were undesirable, their answers might have been affected. Consequently, they might have underreported socially undesirable attitudes and behaviours while enhancing attitudes and behaviours they believed were expected in coping with their life after stroke.

Stroke recovery is multifaceted. Finding the optimal instrument to capture the impact of a psychosocial intervention rather than the expected natural recovery after stroke was challenging. Recovery depends on different mechanisms and treatments at different phases after the acute injury, which range from hours to many months. Although improvement varies among individuals, most patients improve during the first period following the stroke because of acute care treatment and post-lesional plasticity (36).

Another issue is a possible ceiling or floor effect of the outcome measures, which is a known risk with instruments addressing aspects of psychosocial well-being (37). Many participants had no or minor stroke symptoms and limited adverse effects on their daily living activities after their stroke. This outcome resulted in maximum scores on several questions, especially on the SAQOL-39g.

Furthermore, well-being is a subjective phenomenon. Physical sequelae, side-effects of medication, and overall spontaneous improvement may affect how patients answer questions immediately after a stroke compared with 6 months post-stroke. This personal reporting of subjective appraisal introduces the possibility of a response shift into the assessment. A response shift is a change in the meaning of one's self-evaluation due to changes in the respondent's internal standards of measurement and values or a redefinition of the construct by the respondent (38). A response shift may lead to a reconsideration of the current life and affect the outcome measurement scores. This outcome could occur in both groups regardless of adding an intervention and may result in underestimating the treatment effect of psychosocial interventions (38).

The strengths of the study were the thorough development, feasibility and customization of the intervention, which were conducted as recommended by the UK MRC guidance for developing and evaluating complex interventions (13).

In addition, the study was conducted per the rigorous recommendations in the CONSORT statement (39). The intervention fidelity was high and the study was conducted according to protocol.

All personnel involved in the data collection and intervention delivery, underwent a 3-day training programme, individual guidance according to need by members of the research team and participation in group sessions throughout the study.

However, the study had some limitations. We cannot be sure that the training and follow-up of the intervention personnel were sufficient for all of them.

Although the participants represented the largest group of stroke patients admitted to hospitals in Norway, patients with the most severe stroke or aphasia were difficult to include due to early enrolment and difficulties in obtaining informed consent.

The 2 most common reasons for declining to participate, were that they did not feel the intervention suited them or that they had too much going on to commit to participation, but detailed information on the reasons for non-participation were limited due to strict ethics guidelines limiting questions regarding decline.

If a standardized test was not applied in the evaluation of cognitive function (e.g. due to aphasia), the recruiting personnel reported cognitive challenges as "mild", "moderate" or "severe", based on information from the assessments made by the multidisciplinary team. This procedure did not provide reliable information that was applicable to the analysis.

Unfortunately, we do not have a sufficient number of participants to perform subgroup analyses for potentially vulnerable groups, such as those experiencing cognitive challenges, aphasia or lacking social support.

In addition, we questioned whether the control group functioned as intended, because participants in both the intervention and control groups had substantial follow-up time as part of their usual care. The control group also received personal home visits for data collection, which they may have interpreted as an intervention, which thus may have impacted their psychosocial well-being (More details from the control group experiences will be reported as part of the study´s process evalution) . The participation may also have increased the awareness of stroke-related changes and facilitated reflection on psychosocial well-being, changes and symptoms that secondarily affected the outcome.

In conclusion, psychosocial well-being, as measured by the GHQ-28, improved significantly during the first 6 months after stroke in both the intervention and control groups. The results at 6 months indicated that participating in a dialogue-based intervention during the first 6 months post-stroke in addition to usual care did not affect psychosocial well-being. Further research is needed to investigate which factors promote psychosocial well-being after stroke, particularly among patients at high risk of experiencing psychosocial problems.

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The 12-month effects of a dialogue-based intervention after stroke: A randomized controlled trial.

Running Head: Psychosocial well-being after stroke

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Introduction

Stroke is one of the leading causes of death and disability in the adult population worldwide.[1] It may have a devastating effect on people, not only physically, but also emotionally, therefore it is not surprising that psychosocial well-being may be threatened following stroke. Depressive symptoms, anxiety, general psychological distress, and social isolation are prevalent.[2, 3] About one-third of stroke survivors report depressive symptoms, and 20% report anxiety post-stroke.[4, 5] Psychosocial problems persist over time, and the prevalence of post-stroke depression remains high at 25% in the period from 1 to 5 years post-stroke.[4] Psychosocial difficulties may significantly impact long-term functioning and quality of life,[6, 7] reduce the effects of rehabilitation services, and lead to higher mortality.[8] Despite inconclusive evidence,[9, 10] targeted treatments to promote psychosocial adjustment may improve psychosocial well-being.[6, 11] The feasibility work preceding this randomized controlled trial (RCT) suggested that it is possible to promote psychosocial well-being and coping through a dialogue-based intervention.[12-14] We hypothesized that a dialogue-based intervention would lead to higher levels of psychosocial well-being and lower levels of depressive symptoms and anxiety at 12 months post-stroke. Secondary hypotheses were that stroke survivors who received the intervention would experience significantly higher levels of health-related quality of life and sense of coherence at 12 months post-stroke.

Methods

This study was approved by the Regional Committee for Medical and Health Research Ethics, South-East (REC no. 2013/2047) and by the Data Protection Officer serving all participating hospitals (Case number: 2014/1026). Written informed consent was obtained from all participants. Due to strict regulations and conditions for informed consent enforced by Norwegian law, the data set that support the findings of this study is not publicly available. A subset of the data may be made available from the corresponding author upon reasonable request. The study was registered with ClinicalTrials.gov, and the study protocol outlining the full details of the study was published in BMC Psychology in 2018. [14]

Trial design and eligibility

The study was a multicenter, prospective, randomized, assessor-blinded, controlled trial with 2 parallel groups (intervention and standard stroke treatment) and an equal size allocation ratio of 1:1. Eleven hospitals with stroke units or rehabilitation centers in South-Eastern Norway enrolled patients. Eligible participants were aged ≥ 18 years, had suffered an acute stroke within the last 4 weeks, were medically stable, had sufficient cognitive functioning to participate, were able to understand and speak Norwegian before stroke onset, and were able to give informed consent. Exclusion criteria were moderate to severe dementia or other serious physical or psychiatric diseases, and severe receptive or expressive aphasia.

Interventions

Standard stroke treatment

All participants randomized into the study received standard stroke treatment in the acute phase according to Norwegian guidelines.[15] In Norway, patients with minor stroke are typically discharged home with access to interdisciplinary rehabilitation services in the municipality according to need an availability of the service. Services typically include physical therapy and/or occupational therapy and/or speech and language therapy and/or home nursing care. Systematic psychosocial follow up is rarely part of the services provided. Patients with severe stroke are typically discharged to a specialized, in-patient rehabilitation unit for specialized rehabilitation services.

Dialogue-based intervention

Participants randomized to the intervention group were offered a dialogue-based intervention to promote psychosocial well-being. The intervention was referred to as “Psychosocial well-being after stroke”. Psychosocial well-being was defined as consisting of a basic mood of contentment, a self-concept characterized by self-acceptance, usefulness and a belief in one’s abilities. Having social relationships and support, a feeling of loving and being loved in relationships are included in the definition, as well as participation and engagement in meaningful activities beyond oneself [12, 16]. The intervention consisted of 8 individual 1-1 ½-hour sessions between the participants and a specially trained nurse (RN) or occupational therapist (OT) (intervention providers). The intervention providers completed a three-day training program to learn how to guide the sessions and how to work with the participants based on the principles outlined in the protocol. The intervention was delivered in the community, primarily in the participants’ homes. The same intervention provider worked with each participant in all sessions. In line with the protocol, [14] the intervention started shortly after randomization 4 to 8 weeks after stroke onset. It lasted 17 weeks, and the last session was completed within 6 months post-stroke.[14, 17] A guide of stroke-related topics and work-sheets for each session were supplied as part of the intervention.[14] The intervention provider and the participant were encouraged to individually adapt the order of topics and the time in-between sessions to suit the needs of the participants. Additional details on theoretical perspectives underpinning the intervention, themes, and content of the intervention are outlined in the protocol.[14]

Implementation fidelity

Evaluation of implementation fidelity showed that intervention trajectories were individualized in accordance with the protocol and that 80% of the interventions satisfied the criteria for high fidelity adherence.[17] The core components were delivered as planned. Potential moderating factors included participant responsiveness, contextual factors and recruitment.[17]

Outcomes

The primary outcome was emotional distress at 12 months post-stroke measured by the General Health Questionnaire-28 (GHQ-28).[18, 19] For additional details on the scoring of the GHQ-28 in this study, please refer to the online supplementary material (Supplemental file 1). The primary and secondary outcomes and measures are presented in Table 1. Clinical characteristics such as stroke etiology, side localization of the stroke symptoms, stroke severity, cognitive function, and language difficulties were assessed at the hospital and were collected from the patients' medical records.

[Insert Table 1]

Data were collected in-person via structured interviews conducted by trained health care professionals (RNs and OTs) at baseline, 4-6 weeks post-stroke (T1), and at 6 (T2) and 12 (T3) months post-stroke. The participants' ages, sexes, living situations, caring responsibilities, previous illnesses and comorbidities, and current rehabilitation services were recorded in addition to the structured outcome measures. Data collection for the RCT started in November 2014 and was concluded in November 2017.

Sample size

The sample size was determined based on the primary outcome measure GHQ-28. The calculations were based on a repeated measures logistic regression model of the binary output variable "normal mood" (GHQ-28 <5) with 2 measurements for each patient (i.e., one at 6 months and one at 12 months).[14] Based on the results of comparable studies,[20, 21] we deemed an odds ratio of 1.6 or higher between-groups (intervention/control) with normal mood after 6 and 12 months to be clinically relevant. With 80% power across both time points and a significance level α at 0.05, the sample size was estimated to 300 patients (150 per group), which was inflated to a total of 330 to allow for a potential 10% drop-out. [14]

Randomization and masking

A computer-generated block randomization procedure with blocks of 10, stratified by hospital and with an allocation ratio of 5:5, was used in this study. An assistant independent of the research team, prepared opaque randomization envelopes. Two regional trial coordinators carried out the allocation following the baseline assessment (T1). Participants were informed about group allocation immediately. To ensure masking of group allocation at the follow-up assessments (T2 and T3), a message was issued from the trial coordinators to participants with a reminder not to reveal their group allocations to the assessors.

Statistical Analysis

The data were analyzed using an intention-to-treat approach. Missing data were imputed using multiple imputation by chained equations (MICE) in the Statistical Package for the Social Sciences (SPSS). [22, 23] All reported results of the statistical analyses were pooled across 5 imputations based on Rubin's rule [24]. The statistical software R v3.6.1 [25] with package mitools v2.4 was used to pool the results across all 5 imputed data sets. For additional details of the imputation model, please see the online supplementary material (Supplemental file 2). Analyses of the primary and secondary outcomes were performed using logistic regression for binary outcomes and independent and paired samples t-tests for continuous outcomes. A linear mixed model (LMM) was used to assess the primary outcome of psychosocial well-being at 12 months post-stroke. Due to the complexity of the final model, the loss of information when using the dichotomized “normal mood” (GHQ-28 < 5) endpoint instead of a continuous GHQ-28-based endpoint resulted in convergence issues when fitting the binary logistic mixed model. We therefore decided to use the continuous sum-score based on the Likert-scoring of GHQ-28 as the dependent variable. The other factors of the model remained the same as in the predetermined statistical analysis plan. The details of the LMM model are supplied in the online supplementary files (Supplemental file 3). Statistical tests were performed with SPSS, version 25.0 for Windows.[26] All statistical tests were performed as two-sided tests with a significance level of α =0.05.

Results

Between November 2014 and November 2016, 670 individuals were assessed for eligibility and 353 consented to participate (Figure 1). The most common reasons for exclusion were lack of consent (66.6%) and ineligibility (19.9%). There were no significant differences in age and sex between individuals who consented and those who did not.[27] Between consent and the baseline assessment 19 participants were excluded and 12 chose to withdraw from the study. Thus, 322 individuals were assessed at baseline and subsequently allocated to the intervention group (n=166) or the control group (n=156) (Figure 1).

[Insert Figure 1]

Baseline demographics and clinical characteristics were similar in both groups except for depression; a larger proportion in the control group (27.6%) reported depression compared to the intervention group (17.5%) (Table 2).

[Insert Table 2]

There were no between-group differences in psychosocial well-being at 12 months post-stroke (mean difference -0.74, 95% CI: -3.08, 1.60). However, both groups improved significantly on the primary outcome, GHQ-28, at 12 months, relative to the baseline (Table 3).

[Insert Table 3]

The LMM analysis showed that the fixed effect of time was negative for both 6 months and 12 months, which implies a reduced GHQ-28 score overall compared to the baseline, indicating a higher level of psychosocial well-being at 6 months and 12 months post-stroke relative to the baseline (Table 4). Additionally, 5 other explanatory variables had statistically significant fixed effects influencing the GHQ-28 scores. Higher scores on Sense of Coherence (SOC-13) were associated with lower GHQ-28 scores, indicating that higher SOC-13 scores were associated with higher levels of psychosocial well-being. Reporting additional comorbidities, caring responsibilities, fatigue, and depression was associated with higher GHQ-28 scores, which indicated lower psychosocial well-being. Adjusted for all factors in the LMM, the intervention group scored lower (Mean difference: -0.96 points, 95% CI:-2.18, 0.26) on GHQ-28 compared to the control group, however, the between-group differences were not statistically significant (Table 4).

[Insert Table 4]

The secondary outcomes showed no statistically significant between-group difference in depression (Yale), sense of coherence (SOC-13), or stroke-specific, health-related quality of life (SAQOL-39g) at 12 months (Table 3). Self-reported depression showed no between-group difference at 12 months (OR 0.96, 95% CI: 0.55, 1.68). SOC-13 scores appeared to be stable in both groups throughout the study trajectory. The overall score and 1 (intervention group) and 2 (control group) sub-scale scores of the SAQOL-39g showed improvement across the trajectory, but there was no statistically significant difference between the intervention and control groups at 12 months (Table 3).

Discussion

Contrary to our hypotheses, the results of this trial did not demonstrate at the specified statistical significance level that the participants in the intervention group experienced higher levels of psychosocial well-being and lower levels of depressive symptoms and anxiety than participants in the control group at 12 months post-stroke. Nor did the secondary outcomes show statistically significantly higher levels of sense of coherence or higher levels of stroke-specific, health-related quality of life in the intervention group compared with the control group at 12 months post-stroke.

In the following, we will highlight possible reasons for the statistically non-significant results in this RCT, drawing on the results of a comprehensive process evaluation of the RCT and existing research to interpret the outcomes of the trial.[17, 28] Plausible explanations may include flaws in the underlying theoretical assumptions or characteristics of the intervention, the timing of the intervention, the standard care provided to the intervention and control groups, the sample of participants enrolled, or the outcome measures.

Underlying theoretical assumptions and characteristics of the intervention

Based on Antonovsky's theory of sense of coherence,[29] we assumed that an important active ingredient in the intervention would be to support the participants' perceptions of their lives as comprehensible, manageable, and meaningful. We anticipated that the intervention would foster understanding and re-creation of meaning through narrative dialogue, and that the intervention provider could support the participants' coping efforts and development of new life skills through the guided self-determination problem-solving approach.[12, 13] Antonovsky framed sense of coherence as a stable trait that may to some degree be dynamic with fluctuations in periods of threatening life events.[29] Others have shown that sense of coherence is less stable over time than Antonovsky assumed.[30] We hypothesized that the intervention would be able to influence the participants' sense of coherence after a life-threatening event such as stroke, and that a higher sense of coherence would lead to higher levels of psychosocial well-being. This twofold hypothesis was only supported in part. The lack of differences within groups over time and between the intervention and control group does not support the notion that the intervention succeeded in influencing the levels of sense of coherence. On the contrary, the results of the study suggest that this intervention did not influence sense of coherence and that it is a stable construct. However, the results support the notion that a higher sense of coherence is important in the promotion of psychosocial well-being. This knowledge may be important to clinicians who need to be able to identify stroke patients who need extra attention with regards to promoting psychosocial well-being. It may be advisable to screen for sense of coherence during the early post-stroke phase to identify those with lower sense of coherence, who may be more vulnerable to lower psychosocial well-being.

Another assumption made in this intervention was that it would be possible to prevent depression that manifested after stroke due to the increased stress and chaos of trying to cope with the post-stroke changes.[3] For some participants the intervention may have led to decreasing stress and for some to potentially increasing it, depending on their existing stress levels. If the participants did not experience increased stress or challenges in coping in this phase of their adjustment process, we need to consider if the focus on psychosocial challenges in the intervention may have increased rather than decreased their stress. In the future, screening for distress at baseline may be advisable in order to explore whether the intervention may be more appropriate for those with some level of existing stress/distress.

Timing of intervention and standard care

Based on assumptions that early rehabilitation efforts are important to promote psychosocial well-being,[3, 12] the intervention in this trial was designed to be delivered over a period of 5 months starting 4-6 weeks post-stroke and concluding within 6 months post-stroke.[12, 14] The intervention period coincides with a period in which spontaneous functional recovery may peak, [31, 32] and overlaps with a period of comprehensive physical rehabilitation within Norwegian stroke services.[15] The psychosocial intervention provided to the intervention group may not have made a discernable impact in this context with substantial rehabilitation efforts within the regular health care services. The participants received substantial rehabilitation services as part of their standard stroke treatment. At baseline, 68.7% of the intervention group and 63.5% of the control group received one or more rehabilitation services. At 12 months the proportion was still high; 42.3% in the intervention group and 42.1% in the control group. Earlier theoretical work has shown that the physical recovery, daily life adaptation, and normalization, as well as biographical adjustment, occurs simultaneously throughout the first 12 months of the adjustment process after a stroke.[32] However, the focus on physical recovery is more pronounced in the beginning, while the focus on psychosocial issues such as biographical adjustment gains emphasis later in the trajectory. Introducing this intervention on top of the natural recovery and rehabilitation processes may not have added to the adjustment process, or the participants may have been more focused on other parts of their adjustment than that of a psychosocial nature. For some it may even be that the early introduction of this intervention led to an accelerated focus on psychosocial issues.

It is important to consider whether the extra attention given to the psychosocial issues in the intervention group came at an inappropriate time in the participants' stroke recovery and whether we may have increased the awareness on psychosocial difficulties rather than prevented them. Other studies have shown successful results in promoting normal moods when introducing early psychosocial support by providing motivational interviewing to support and build patients' motivation to adjust and adapt to having had a stroke.[21] Motivational interviewing aimed to promote self-efficacy as opposed to problem solving. The patients raised the issues they wanted to discuss themselves instead of having topics outlined for each meeting.[20] Compared to the problem-solving nature of the intervention tested in this RCT, motivational interviewing may have been more aligned with the patients' main focus at the time of the intervention.

The sample of participants enrolled

The feasibility work done during the development of the intervention failed to clearly identify patient groups who would potentially benefit from this intervention. Wide inclusion criteria were applied in the RCT, which may have inadvertently resulted in the enrolment of participants who did not particularly need this kind of intervention. The process evaluation that was conducted alongside the trial showed that not all participants expected a personal benefit and that a key motivation to participate was to contribute to research and to help other stroke survivors.[28] Despite this observation, the majority of the participants who participated in the qualitative interviews as part of the process evaluation found the intervention useful and found that it facilitated their post-stroke adjustments.[28] Some participants in the control group reported that the assessment interviews facilitated reflection and adjustment, and some indicated that allocation to the control group and the themes raised in the assessment interviews influenced their help-seeking behavior outside the trial.[33]

It is still important to identify sub-groups of the stroke population who might benefit from a psychosocial intervention to promote well-being. Patients who reported depressive symptoms, fatigue, comorbidities and caring responsibilities were prone to lower levels of psychosocial well-being in this study. Earlier studies have shown that emotional distress at 1 month post-stroke, higher stroke severity, and communication impairments predict emotional distress during the first 6 months post-stroke.[34] Studies exploring predictors of emotional distress and well-being in a longer post-stroke perspective have found that higher age (> 65), independence in mobility, having social support, and being employed are important predictors of well-being.[35] Conversely dependency in activities of daily living (i.e., toileting) predict emotional distress 2-5 years post-stroke.[35] Identifying patients with the characteristics identified in this and other studies may be especially important in clinical settings to identify those who may need closer attention and follow-up with regards to psychosocial well-being.

Outcome measures

There is a need to consider whether the chosen outcome measures were appropriate to detect the kind of change the intervention targeted. The change in emotional distress in both the intervention and control groups across the trajectory indicated that the GHQ-28 was sensitive to change. There was a substantial increase in the proportion of participants with GHQ-28 scores < 5 in both groups. Furthermore, the level of improvement exceeded the findings in a similar study in which motivational interviewing was provided post-stroke.[20, 21] However, the sensitivity of the GHQ-28 does not necessarily mean it was the most suitable outcome measure in this study. The intervention was aimed at promoting psychosocial well-being, so using an instrument that measures emotional stress and reduction in depressive symptoms to enable comparison with similar studies may not have been an ideal choice. Including a measure that targeted well-being, such as the Warwick-Edinburgh Mental Wellbeing Scales (WEMWBS), could have strengthened the study. The WEMWBS was developed to enable the measuring of mental wellbeing in the general population and to enable the evaluation of interventions that aim to improve mental well-being.[36] Based on the definition of psychosocial well-being used in the development of this intervention, including outcome measures that assess participation in meaningful activities may have added important data to evaluate the outcomes of the intervention. The lack of such an outcome measure was a limitation to this study. Alternative outcome measures for quality of life, participation and well-being should be explored in future research.

Strengths and limitations

A strength in this study was the systematic development and feasibility testing of the intervention prior to full scale effectiveness tests in this RCT. The trial was conducted in a rigorous manner following the Consolidated Standards of Reporting Trials (CONSORT) statement.[37] Additionally, the comprehensive process evaluation, including the evaluation of implementation fidelity that was conducted alongside the trial, was an important advantage in documenting the trial implementation and in understanding trial outcomes. All intervention providers and assessors participating in the study were required to complete training prior to their participation, which was important in establishing uniform delivery of the intervention and the assessment interviews. Completing assessment interviews and intervention sessions with a parallel goal of individualization and uniform delivery may, however, have been a challenging concept and a limitation in this study. Participating in supervision sessions was voluntary for intervention providers, and the follow-ups of the assessors was also based on a voluntary and as-needed basis. In retrospect, mandatory follow-up and supervision may have been warranted so assure uniform delivery. Another limitation in this study was the difficulties in enrolling patients with more severe stroke symptoms and aphasia. However, the sample included in this study represents the largest group of stroke patients admitted to hospitals in Norway.[27] The RNs and OTs who enrolled participants reported that it was difficult to assess whether patients with aphasia were able to consent. Ensuring informed consent was perceived to be too time-consuming in the clinical setting, resulting in few participants with aphasia. Furthermore, enrolment personnel found it difficult to approach the patients with more severe stroke during the short time that they were treated in the stroke unit. These challenges emphasized the need for dedicated personnel that were not involved in other clinical duties while simultaneously enrolling patients to the trial.

Conclusions

The results of this trial did not demonstrate at the specified statistical significance level that the participants in the intervention group experienced higher levels of psychosocial well-being and lower levels of depressive symptoms and anxiety than participants in the control group at 12 months post-stroke. We did not find sufficient evidence to support the implementation of the intervention in its current form based on the outcome measures used in this RCT. Patients reporting depressive symptoms, fatigue, comorbidities, and caring responsibilities were prone to lower levels of psychosocial well-being. The results support the notion that a higher sense of coherence is important in the promotion of psychosocial well-being. However, the inclusion criteria in this study may have been too wide, and further research is needed to confirm which sub-groups of stroke patients need a psychosocial intervention and at what time post-stroke such an intervention is appropriate.

Clinical messages

- Patients reporting depressive symptoms, fatigue, comorbidities, and caring responsibilities were prone to lower levels of psychosocial well-being.
- Patients experiencing higher sense of coherence reported higher levels of psychosocial well-being.
- Screening for sense of coherence in the early post-stroke phase may be advisable to identify patients vulnerable to lower psychosocial well-being.

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Declaration of Conflicting Interests

The authors declare that there are no conflicts of interest.

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Trial registration

Clinical Trial Registration-URL: http://www.clinicaltrials.gov. Unique identifier: NCT02338869. Date of registration: 10/4/2014.

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Online Supplement

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Table 1: Outcome measures applied in the study

Primary outcome	**Measure**	**Description**	**Assessment**[1]
Emotional distress	The General Health Questionnaire-28 (GHQ-28) [18, 19]	Scaled 28-item self-report questionnaire measuring emotional distress. Four sub-scales identified in psychometric tests (somatic symptoms, anxiety and insomnia, social dysfunction and severe depression) [18, 27].	T1, T2, T3
Secondary outcomes	**Measure**	**Description**	**Assessment**
Health-related quality of life	Stroke and Aphasia Quality of Life Scale-39 generic stroke version (SAQOL-39g) [38, 39]	Disease-specific health-related quality of life scale, measures patient's perspective of stroke's impact on 'physical', 'psychosocial' and 'communication' domains.	T1, T2, T3
Sense of coherence	Sense of Coherence scale (SOC-13) [29]	Self-report questionnaire, 13 components, measuring the main concepts in the SOC theory; coherence, meaningfulness and manageability. 13 items scored on a Likert scale, ranging from 1–5. Higher scores indicate a stronger SOC.	T1, T2, T3
Depression	The Yale Brown single item questionnaire (Yale) [40, 41]	Self-reported presence or absence of depression. One yes/ no question.	T1, T2, T3
Characteristics of sample	**Measure**	**Description**	**Assessment**
Fatigue	Fatigue Questionnaire-2 (FQ-2) [42, 43]	Self-reported presence or absence of fatigue. One yes/ no question. If yes; indication of duration of symptoms.	T1, T2, T3
Aphasia	The Ullevaal Aphasia Screening Test (UAS) [44]	Screening for aphasia.	T1
Stroke severity/ neurological deficit	National Institutes of Health Stroke Scale (NIHSS) [45]	An 11-item scale used by healthcare providers to objectively quantify the impairment caused by a stroke.	T0
Cognitive function	Mini Mental State Evaluation (MMSE) [46]	30-point test that is used to measure potential cognitive impairment, a score below 24 indicates cognitive impairment ranging from mild (19-23), moderate (10-18), and severe (≤ 9).	T0

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[1] T0=Data from acute phase collected from patient record, T1=Baseline assessment at 4-6 weeks post-stroke, T2=Assessment at 6 months post-stroke, T3=Assessment at 12 months post-stroke

Table 2: Baseline demographics and clinical characteristics

	Intervention group (n=166)	**Control group (n=156)**
Baseline demographics		
Age, years, *mean (SD)*	66.8 (12.1)	65.7 (13.3)
Sex		
Female	67 (40.4)	65 (41.7)
Male	99 (59.6)	91 (58.3)
Living conditions		
Living with someone	117 (70.5)	101 (63.7)
Living alone	49 (29.5)	55 (35.3)
Have caring responsibilities	37 (22.3)	36 (23.1)
Underage children	26 (15.7)	22 (14.1)
Spouse or cohabiting partner	10 (6.0)	6 (3.8)
Parents	2 (1.2)	6 (3.8)
Other	2 (1.2)	6 (3.8)
Clinical characteristics		
Stroke type (n=147; 144)		
Infarction	128 (87.1)	136 (94.4)
Haemorrhage	19 (12.9)	8 (5.6)
Stroke symptom localization (n=142; 136)		
Right	65 (45.8)	56 (41.2)
Left	70 (49.3)	74 (54.4)
Bilateral	7 (4.9)	6 (4.4)
Feeling sad or depressed (Yale)	29 (17.5)	43 (27.6)
Feeling fatigued (FQ-2) (n=165; 156)	88 (53.3)	87 (55.8)
NIHSS, *median (IQR)* (n=126; 114)	4 (1-7)	2.5 (1-6)
NIHSS categorized scores (n=126; 114)		
Mild (0-5)	85 (67.5)	85 (74.6)
Moderate (6-10)	28 (22.2)	17 (14.9)
Moderate to severe (11+)	13 (10.3)	12 (10.5)
MMSE, *median (IQR)* (n=63; 65)	27 (25-29)	28 (26-30)
UAS (n=163;156) *median (IQR)*	52 (50-52)	52 (50-52)
Receive one or more rehabilitation services at baseline	114 (68.7)	99 (63.5)
Physical therapy	98 (59.0)	88 (56.4)
Occupational therapy	73 (44.0)	62 (39.7)
Speech and language therapy	30 (18.1)	27 (17.3)
Home nursing care	56 (33.7)	46 (29.5)
Psychologist/psychiatrist	14 (8.4)	11 (7.1)
Other	22 (13.3)	14 (9.0)
Comorbidities		
No reported comorbidities	31 (18.7)	32 (20.5)
Hypertension	71 (42.8)	64 (41.0)
Heart disease	49 (29.5)	39 (25.0)
Diabetes	22 (13.3)	21 (13.5)
Stroke	22 (13.3)	25 (16.0)
Cancer	21 (12.7)	21 (13.5)
Musculoskeletal diseases	21 (12.7)	22 (14.1)
Rheumatic diseases	16 (9.6)	15 (9.6)
Depression	13 (7.8)	16 (10.3)
Gastrointestinal diseases	12 (7.2)	11 (7.1)
Lung disease	8 (4.8)	10 (6,4)
Other reported comorbidities	16 (9.6)	15 (9.6)

Values are n (%) unless stated otherwise. SD indicates standard deviation, IQR indicates interquartile range, NIHSS indicates National Institutes of Health Stroke Scale, MMSE indicates the Mini Mental State Exam. UAS indicates Ulleval Aphasia Screening. Comorbidities and rehabilitation services were self-reported by participants.

Table 3: Primary and secondary outcomes at baseline and 12-month follow up, by group

	Intervention group (n=166)			**Control group (n=156)**			***Between group differences at 12 months (T3)***	
Outcomes	**T1**	**T3**	***P* Value**[*]	**T1**	**T3**	***P* Value**[*]		***P* Value**[†]
GHQ-28 (<5)[‡] (N (%))	50 (30.1)	109 (65.7)	<0.001[§]	46 (29.5)	103 (66.0)	<0.001[§]	0.98 (0.62, 1.57)	0.946[‖]
GHQ-28 (sum, range: 0-84)[‡] (Mean (SE))	25.9 (0.84)	20.6 (0.84)	<0.001[#]	28.5 (0.98)	19.9 (0.85)	<0.001[#]	-0.74 (-3.08, 1.60)	0.537[**]
Somatic symptoms (Range: 0-9) (Mean (SE))[***]	2.4 (0.18)	1.8 (0.15)	0.002[#]	2.8 (0.20)	1.9 (0.15)	<0.001[#]	0.10 (-0.31, 0.52)	0.618[**]
Anxiety and insomnia (Range: 0-33) (Mean (SE))[***]	8.3 (0.43)	7.3 (0.43)	0.033[#]	9.0 (0.49)	7.0 (0.45)	<0.001[#]	-0.30 (-1.55, 0.95)	0.634[**]
Social dysfunction (Range: 0-30) (Mean (SE))[***]	14.8 (0.38)	10.8 (0.36)	<0.001[#]	15.7 (0.42)	10.4 (0.32)	<0.001[#]	-0.36 (-1.32, 0.60)	0.457[**]
Severe depression (Range: 0-12) (Mean (SE))[***]	0.5 (0.10)	0.8 (0.13)	0.030[#]	0.9 (0.17)	0.6 (0.11)	0.103[#]	-0.18 (-0.52, 0.17)	0.314[**]
Feeling sad or depressed (Yale) (N(%))[‡]	29 (17.4)	38 (22.9)	0.279[§]	43 (27.6)	37 (23.7)	0.444[§]	0.96 (0.55, 1.68)	0.890[‖]
Sense of coherence (SOC-13, sum, range: 13-65**)** (Mean (SE))[‡]	50.6 (0.42)	50.6 (0.62)	0.936[#]	50.4 (0.47)	51.0 (0.56)	0.268[#]	0.43 (-1.09, 1.94)	0.581[**]
Quality of Life (SAQOL-39g, mean, range: 1-5**)** (Mean (SE))[‡]	4.30 (0.04)	4.36 (0.04)	0.077[#]	4.24 (0.05)	4.43 (0.04)	<0.001[#]	0.06 (-0.04, 0.17)	0.247[**]
Physical domain (Range: 1-5) (Mean (SE))[‡]	4.24 (0.07)	4.50 (0.05)	<0.001[#]	4.21 (0.08)	4.57 (0.05)	<0.001[#]	0.06 (-0.07, 0.20)	0.364[**]
Communication domain (Range: 1-5) (Mean (SE))[‡]	4.75 (0.04)	4.73 (0.04)	0.542[#]	4.74 (0.05)	4.79 (0.04)	0.338[#]	0.06 (-0.05, 0.16)	0.271[**]
Psychosocial domain (Range: 1-5) (Mean (SE))[‡]	3.90 (0.06)	3.85 (0.07)	0.501[#]	3.76 (0.06)	3.93 (0.07)	0.017[#]	0.07 (-0.11, 0.25)	0.447[**]

---

[*] Within group differences from T1 to T3.

[†] Between group differences at T3.

[‡] Reporting pooled results of imputed data.

[§] Logistic regression, p-value.

[ǀ] Logistic regression, (OR (95% CI)).

[#] Paired samples t-test, p-value.

[**] Independent samples t-test, (mean difference (95% CI)).

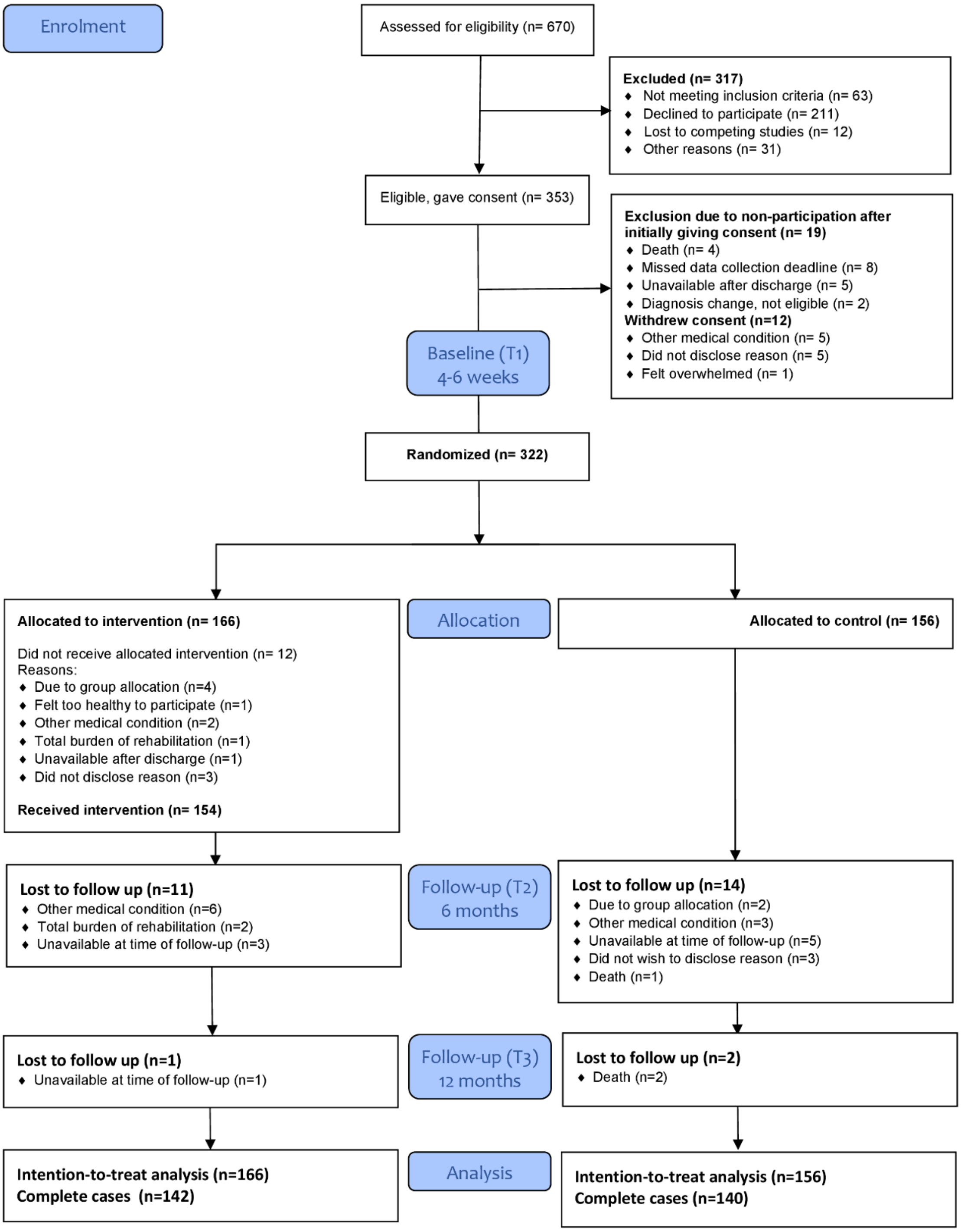
[***] Reporting pooled results of imputed data, new factor structure sum score.

Table 4: Linear mixed model showing fixed effect coefficients

			95% CI		
	Coefficient	**S.E**	**Lower**	**Upper**	**p-value**
Intercept	*54.551*	*3.472*	*47.746*	*61.355*	*<0.001*
Time					
Baseline (Ref.)					
6-months post-stroke	-5.648	0.560	-6.745	-4.551	<0.001
12-months post-stroke	-6.490	0.588	-7.642	-5.338	<0.001
Group allocation					
Control Group (Ref.)					
Intervention group	-0.956	0.622	-2.175	0.264	0.125
Sex					
Female (Ref.)					
Male	0.124	0.647	-1.145	1.393	0.848
Age at admission	-0.027	0.024	-0.073	0.019	0.249
Stroke etiology					
Infarction (Ref.)					
Hemorrhage	0.804	1.131	-1.414	3.021	0.477
Stroke symptom localization					
Right (Ref.)					
Left	0.390	0.673	-0.940	1.719	0.563
Bilateral	1.433	2.022	-2.539	5.405	0.479
Stroke severity (NIHSS)	0.117	0.097	-0.075	0.309	0.228
Live with partner or other	-0.183	0.671	-1.499	1.133	0.785
Comorbidity	1.792	0.716	0.388	3.196	0.012
Rehabilitation Services	0.798	0.617	-0.410	2.007	0.195
Caring responsibilities	2.599	0.873	0.889	4.309	0.003
Depression (Yale)	5.514	0.951	3.650	7.377	<0.001
Fatigue (FQ-2)	4.091	0.644	2.829	5.352	<0.001
Sense of coherence (SOC-13)	-0.638	0.058	-0.753	-0.524	<0.001

Dependent variable: GHQ-28, sum-score range from 0-84 (Likert scoring). N=322.

Figure 1: Participant recruitment and retention flow chart



Appendices

1. Ethical approval by Regional Committees for Medical and Health Research Ethics (REC) South East (case number: 2013/2047) (in Norwegian)
2. Research approval from the Data Protection Officer serving all participating hospitals (Case number: 2014/1026) (in Norwegian)
3. Information letter and consent for participation (in Norwegian)

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK sør-øst	Tor Even Svanes	22845521	18.12.2013	2013/2047/REK sør-øst C
			Deres dato:	**Deres referanse:**
			05.11.2013	

Vår referanse må oppgis ved alle henvendelser

Til Siren Eriksen Kouwenhoven

2013/2047 Psykososial helse etter hjerneslag

Forskningsansvarlig: Universitetet i Oslo, Oslo universitetssykehus
Prosjektleder: Siren Eriksen Kouwenhoven

Vi viser til søknad om forhåndsgodkjenning av ovennevnte forskningsprosjekt. Søknaden ble behandlet av Regional komité for medisinsk og helsefaglig forskningsetikk (REK sør-øst C) i møtet 03.12.2013. Vurderingen er gjort med hjemmel i helseforskningsloven (hfl.) § 10, jf. forskningsetikklovens § 4.

Prosjektomtale

De fysiske, kognitive, følelsesmessige og kommunikative konsekvensene av hjerneslag er sammensatte. Flere studier har vist at strukturerte samtaler med helsepersonell kan være til god hjelp for å fremme psykisk helse etter slag. Slagrammede er i en risikogruppe for å utvikle angst, depresjon og sosial isolasjon, og afasirammede er ofte utelatt fra forskning. Med dette som bakgrunn er det utviklet en samtalebasert psykososial intervensjon. Intervensjonen er utprøvd i flere pilotstudier. Hensikten med denne studien er å evaluere intervensjonen på en større gruppe av personer som har gjennomgått hjerneslag, med og uten afasi, gjennom en randomisert, kontrollert studie. Deltagere skal være over 18 år, kognitivt i stand til å delta i intervensjonen, medisinsk stabile, kan forstå og kommunisere på norsk, og ikke ha annen alvorlig lidelse. Deltagerne fordeles i to grupper, en intervensjonsgruppe som følges med intervensjon i tiden 1-6 måneder etter slaget og en kontrollgruppe.

Vurdering

Komiteen mener dette er en grundig og godt forberedt søknad, og har ingen innvendinger til designet i studien.

Vedtak

Prosjektet godkjennes med hjemmel i helseforskningslovens §§ 9 og 33.

Tillatelsen er gitt under forutsetning av at prosjektet gjennomføres slik det er beskrevet i søknaden og protokollen, og de bestemmelser som følger av helseforskningsloven med forskrifter.

Tillatelsen gjelder til 31.12.2018. Av dokumentasjons- og oppfølgingshensyn skal prosjektopplysningene likevel bevares inntil 31.12.2023. Opplysningene skal lagres avidentifisert, dvs. atskilt i en nøkkel- og en opplysningsfil. Opplysningene skal deretter slettes eller anonymiseres, senest innen et halvt år fra denne dato.

Personvernombudet for forskning og kvalitetssikring
Kompetansesenter for personvern og informasjonssikkerhet
Oslo universitetssykehus HF

PERSONVERNOMBUDETS UTTALELSE

Til:	Siren Eriksen Kouwenhoven Unni Sveen Forskningsansvarlige ved SI, LDS og VV
Kopi:	
Fra:	Personvernombudet for forskning og kvalitetssikring
Saksbehandler:	Helge Grimnes
Dato:	18.02.2014
Offentlighet:	Ikke unntatt offentlighet
Sak:	Personvernombudets uttalelse om innsamling og behandling av personopplysninger
Saksnummer/ Personvernnr:	2014/1026

Personvernombudets uttalelse om innsamling og behandling av personopplysninger i prosjektet «*Psykososial helse etter hjerneslag*»

Viser til innsendt melding om behandling av personopplysninger / helseopplysninger. Meldingen er sendt til personvernombudet ved Oslo universitetssykehus, som også er personvernombud for forskning og kvalitetssikring ved Sykehuset Innlandet, Vestre Viken HF, Lovisenberg diakonale sykehus m.fl. Meldingen er et ledd i foretakenes interne kvalitetskontroll av informasjonssikkerheten i helseforskningsstudier. Det følgende er et formelt svar på meldingen. Denne dekker de foretakene som er nevnt i meldingen (OUS, VV, SI og LDS). Forutsetningene nedenfor må være oppfylt før rekruttering av pasienter til studien kan starte.

Det vises til REKs godkjenning 05.11.2013 (saksnr, 2013/2047). Personvernombudet har vurdert den planlagte databehandlingen av personopplysninger / helseopplysninger til å tilfredsstille de interne retningslinjer som er etablert for informasjonssikkerhet i forskning ved nevnte foretak. Personvernombudet har ingen innvendinger til gjennomføringen av studien.

Med vennlig hilsen
for Personvernombudet for forskning og kvalitetssikring

Helge Grimnes
Personvernrådgiver
Kompetansesenter for personvern og informasjonssikkerhet
Stab pasientsikkerhet og kvalitet
Oslo universitetssykehus HF

Epost: personvern@oslo-universitetssykehus.no
Web: www.oslo-universitetssykehus.no/personvern

Forskningsprosjektets data skal oppbevares forsvarlig, se personopplysningsforskriften kapittel 2, og Helsedirektoratets veileder for Personvern og informasjonssikkerhet i forskningsprosjekter innenfor helse- og omsorgssektoren.

Komiteens avgjørelse var enstemmig.

Sluttmelding og søknad om prosjektendring
Prosjektleder skal sende sluttmelding til REK sør-øst på eget skjema senest 30.06.2019, jf. hfl. § 12. Prosjektleder skal sende søknad om prosjektendring til REK sør-øst dersom det skal gjøres vesentlige endringer i forhold til de opplysninger som er gitt i søknaden, jf. hfl. § 11.

Klageadgang
Du kan klage på komiteens vedtak, jf. forvaltningslovens § 28 flg. Klagen sendes til REK sør-øst. Klagefristen er tre uker fra du mottar dette brevet. Dersom vedtaket opprettholdes av REK sør-øst, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag for endelig vurdering.

Med vennlig hilsen

Britt-Ingjerd Nesheim
prof. dr. med.
leder REK sør-øst C

Tor Even Svanes
seniorrådgiver

Kopi til:
Marit Kirkevold, UiO: marit.kirkevold@medisin.uio.no
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UiO Det medisinske fakultet
Universitetet i Oslo

Forespørsel om å være med i forskningsprosjektet

«Psykososial helse etter hjerneslag»

Dette er en forespørsel **om du vil delta** i et **forskningsprosjekt** om rehabilitering etter hjerneslag.

Prosjektet gjennomføres av forskere fra Oslo Universitetssykehus og Universitetet i Oslo, i samarbeid med Høgskolen i Hedmark og Høgskolen i Narvik, og er knyttet til Forskningssenter for habiliterings- og rehabiliteringstjenester (CHARM).

BAKGRUNN:

Mange slagrammede opplever at **rehabilitering er krevende.**

Forandringer i hukommelse og konsentrasjon, fysisk funksjon, språk og tale, eller følelsesmessige reaksjoner **er vanlig** etter hjerneslag.

En forskergruppe har utviklet et **oppfølgingsprogram med samtaler** som vi tror kan være til hjelp for å mestre forandringene. Programmet ble prøvd ut i 2007-2009. Erfaringene var positive. Forskning fra andre land viser at **samtaler** med helsepersonell kan være **til god hjelp** i rehabiliteringen. Vi vil nå evaluere programmet for en større gruppe slagrammede. For å undersøke om oppfølgingsprogrammet kan være et godt tilbud i fremtiden, vil vi sammenlikne det nye programmet med vanlig oppfølging etter hjerneslag. De som er med i prosjektet blir tilfeldig i en av to oppfølgingsgrupper (se under).

HVA innebærer det å være med?

Gruppe1: Du får **vanlig oppfølging** etter hjerneslag. Du deltar i **intervju**.

Gruppe 2: Du får **vanlig oppfølging** etter hjerneslag og i tillegg oppfølging med **8 samtaler** fordelt over 5 måneder. Du deltar i **intervju**.

Samtalene (gjelder bare gruppe 2):

- En **spesialopplært sykepleier** eller person med annen relevant helsebakgrunn leder samtalene.
- Det brukes **arbeidsark med ulike temaer**
- Du kan ha med deg et **familiemedlem,** eller en annen til en eller flere samtaler
- Møtene vil foregå hver 14. dag i starten, og så en til to ganger i måneden etter hvert
- Hvert møte vil vare ca. 1 - 1,5 time
- Det første møtet avtales 1 måned etter hjerneslaget
- Den som skal følge deg opp **tar kontakt** med deg for videre avtaler
- De 4 første møtene er individuelle. De 4 neste møtene **kan** være i gruppe, hvis du ønsker det, og det er mulig.
- De fleste møtene vil foregå **hjemme hos deg** eller der du ønsker det.

Intervju (gjelder både gruppe 1 og 2)

- Alle deltagere blir **intervjuet 3 ganger** ved hjelp av spørreskjemaer
- **Intervjuene vil dreie seg om** din opplevelse av helse, mestring, livskvalitet og helsetjenester
- Intervjuene foregår 1, 6 og 12 måneder etter hjerneslaget
- Hvis du har problemer med å snakke, forstå tale eller skrift, lese eller skrive, blir du vurdert av en logoped før første intervju
- En forsker med helsefaglig bakgrunn vil foreta intervjuene
- Det blir **innhentet opplysninger** om hjerneslaget du har hatt. Andre opplysninger vi spør om er blant annet alder, kjønn, sivil status, utdanning, yrke, bolig, hjerneslagets omfang og symptomer.

HVILKEN nytte er det i å delta?

- Alle deltagere får **flere møter med helsepersonell** med samtaler og/eller intervju
- Både intervjuene og de ekstra samtalene kan bidra til **ny kunnskap** og bevissthet om det å være rammet av hjerneslag
- De som deltar på de 8 samtalene får ekstra **hjelp til å mestre** de psykososiale konsekvensene av hjerneslaget
- Du er med i **forskning** som kan hjelpe andre slagrammede

HVILKEN sikkerhet har den som deltar?

- Det er **ingen fare** forbundet med å delta
- Det er helt **frivillig** å være med
- Du **kan trekke deg** fra prosjektet når som helst uten å oppgi grunn, eller at det får noen negative konsekvenser for deg
- Du har rett til **innsyn i opplysningene** om deg selv, og du kan be om at feil rettes eller opplysninger slettes.
- Sykepleieren (helsearbeiderne) har **taushetsplikt**
- Opplysninger om deg og familien blir behandlet **konfidensielt**
- Det er kun **autorisert personell** som har tilgang til opplysningene
- Opplysninger lagres **uten navn** og oppbevares i låsbare skap på Universitetet i Oslo
- Alle opplysninger om deg **blir slettet** etter at prosjektet er ferdig og materialet analysert
- Det vil bli skrevet en **rapport og flere vitenskapelige artikler** om hele prosjektet
- Ingen opplysninger kan føres tilbake til deg

Er det noe du lurer på kan du kontakte prosjektansvarlig eller prosjektleder.

Prosjektansvarlige:

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Med vennlig hilsen

Marit Kirkevold | Unni Sveen

Marit Kirkevold
(Prosjektansvarlig)

Unni Sveen
(Prosjektansvarlig)

Oslo universitetssykehus

Høgskolen i Hedmark

Høgskolen i Narvik

Samtykkeerklæring

Jeg er **muntlig og skriftlig informert** om hensikten med prosjektet, hva det går ut på og hva deltagelse innebærer for meg.

JA 👍 **NEI** 👎

Jeg har fått informasjon om at deltagelse betyr at:

- Jeg er **med på intervju** 1, 6 og 12 måneder etter hjerneslaget

JA 👍 **NEI** 👎

- Det innhentes **opplysninger om mitt hjerneslag** fra pasientjournal, helsepersonell eller pårørende

JA 👍 **NEI** 👎

- Hvis jeg blir med i gruppe 2, deltar jeg i **8 samtaler med helsepersonell** fordelt over **fem måneder**

JA 👍 **NEI** 👎

- Jeg forstår at alle **opplysninger** som samles inn om meg **behandles konfidensielt.**

JA 👍 **NEI** 👎

- Jeg kan når som helst **trekke meg fra prosjektet** uten å oppgi grunn

JA 👍 **NEI** 👎

Jeg er **villig til å delta** i studien

JA

NEI

(Signert av prosjektdeltaker, dato)

Jeg bekrefter å ha gitt informasjon om studien

(Signert, rolle i studien, dato)

Kontaktinformasjon:

Pasient (navn, adresse, telefon):

Pasientens eksemplar

Jeg er **villig til å delta** i studien

JA  **NEI** 

(Signert av prosjektdeltaker, dato)

Jeg bekrefter å ha gitt informasjon om studien

(Signert, rolle i studien, dato)

Kontaktinformasjon:

Pasient (navn, adresse, telefon):

Prosjektets eksemplar
-RIV AV-