BMJ Open

Ensemble programme for early intervention in informal caregivers of psychiatric adult patients: a protocol for a randomised controlled trial

Shyhrete Rexhaj [iD],[1] Shadya Monteiro [iD],[1] Philippe Golay [iD],[2]
Claire Coloni-Terrapon [iD],[1] Daniel Wenger [iD],[1] Jérôme Favrod [iD] [1]

Check for updates

[1]La Source, School of Nursing, University of Applied Sciences and Arts Western Switzerland, HES-SO, Lausanne, Vaud, Switzerland
[2]Community Psychiatry Service, Department of Psychiatry, Lausanne, CHUV, Lausanne, VD, Switzerland

Correspondence to
Dr Shyhrete Rexhaj;
s.rexhaj@ecolelasource.ch

ABSTRACT

Introduction Informal caregivers play a major role in the support and maintenance of community patients with severe psychiatric disorders. A pilot study showed that an individualised brief intervention such as the Ensemble programme leads to significant improvements in psychological health state and optimism.

Methods and analysis This randomised controlled trial aims to compare the efficacy of using Ensemble in improving informal caregivers' psychological health states and the ability to play an active role in their situations with that of support as usual. Improvements on the psychological health global index will be measured three times (T0-pre, T1-post and T3 2 months follow) with standardised questionnaires (the Global Severity Index of Brief Inventory Symptoms, the Life Orientation Test-Revised, the 36-item Medical Outcome Study Short-Form Health Survey and the French Zarit Burden Interview). Differences between groups in post-test and pretest values will be examined using an analysis of covariance for each outcome variable. The severity of illness measured by the Social and Occupational Functioning Assessment Scale will also be collected at T0 and T2 to compare eventual patient improvements. At the end of the programme, the experiences of the 20 patients participating in the Ensemble programme will be evaluated qualitatively.

Ethics and dissemination The research protocol received full authorisation from the Human Research Ethics Committee of the Vaud state, Switzerland. The principal paper will concern the results of the experimental design used to test the Ensemble programme. The research team will prioritise open access publications.

Trial registration number NCT04020497

INTRODUCTION

Care in the community has greatly improved the conditions of people with severe and persistent mental disorders. In this context, informal caregivers are significant partners, and appropriate support must be provided.[1 2] Although family and informal caregiver play a vital role in the early detection of mental health disorders and facilitating access to care, it is not easy for health professionals

Strengths and limitations of this study

► This is the first randomised controlled trial in Switzerland to test Ensemble, an active individualised programme for the informal caregivers of people suffering from a psychiatric disorder in comparison to controls.
► The Ensemble programme is brief (five sessions, once a week), tailored and offers different practical tools for informal caregivers to improve their health, quality of life and ability to cope with the patient's illness.
► The intervention provider endorses a facilitator role to improve informal caregivers' empowerment.
► Tailored early interventions are recommended because actual support given in practice lacks consideration of the informal caregivers' specific needs and should not depend on only the patient's treatment.
► No comparison with an active intervention (as a psychoeducation programme) presents a limitation.

to develop such partnerships.[3] Several studies have underscored the importance of supporting informal caregivers in their capacities to integrate their new caregiver's role.[4–6] Möller-Leimkühler demonstrated that informal caregivers need emotional support as soon as the diagnosis is made.[7] Emotional support is essential in the moratorium stage of recovery.[8 9] When a patient's close informal caregiver first learns about a diagnosed psychiatric disorder, he or she might feel a range of emotions and might exhibit varied reactions linked to this stage (eg, revolt, confusion, hopelessness, denial). In the second stage of recovery, relatives develop a greater awareness of the disorder, although this awareness can raise significant fears about the future. Feelings such as guilt, avoidance or a desire to give up can emerge.[8 9] It is, therefore, critical to intervene early during the first two stages of recovery to promote the health of informal

caregivers and to reorient them away from unsuccessful coping strategies that might be harmful in the long term.[8–10] Informal caregivers often feel helpless, lack confidence regarding how to help the sufferer and experience shock when faced with a close relative suffering psychologically.[11 12] They can experience significant distress since they lack support and practical tools for managing the situation.[4] Feelings of helplessness and uncertainty can be compounded by a lack of knowledge of the disorder and not knowing how to help the patient.[13] Informal caregivers could become isolated due to the harmful effects of stigmatisation, which can also have negative impacts on their health.[14] Indeed, informal caregivers of people with severe psychiatric disorders can experience serious situations with potential negative consequences for their quality of life, their own health and the health of the patient.[15–17] In order to help them developing effective coping strategies, interventions must be contextualised, culturally adopted and specified to the informal caregiver's role in order to fill individualised needs.[18 19] These diverse issues are crucial for understanding how to better support informal caregivers. The results of a meta-analysis of patients suffering from schizophrenia spectrum disorders showed that most programmes include information about the disease and focus on the development of communication and coping skills to reduce the negative effects on caregivers.[20] Interventions for bipolar disorder are mainly based on the 'vulnerability-stress model' and include information about how this illness impacts relatives, as well as training sessions on communication skills and problem-solving techniques.[21] Interventions tested in a study of depressive disorders included theoretical input on aetiology, and they focused on the causes of depression, depressive symptoms, treatment and the development of coping strategies.[22] Previous studies have also identified that informal caregivers need tailored knowledge of the patient's illness, clarification of their roles and responsibilities, better control over their own lives and effective collaboration with health professionals.[4–7 12 23 24] Additionally, scientific data recommend adjusting caregivers' support according to the phase and severity of illness, as well as the caregiver's sociodemographic characteristics.[7] Most of the interventions published in the literature have focused on the ill family member and his or her support but not on the specific needs of informal caregivers as the core intervention. Lobban *et al* presented an individualised programme that is self-managed and specific for relatives of people with recent-onset psychosis.[11] To reduce the gap between scientific recommendations and actual practice, a tailored intervention called Ensemble (Together in English) was developed and tested in a pilot study.[3 25] The results of this pilot study showed that informal caregivers experience many difficulties and unmet needs regarding their caregiver role, as well as painful emotions, while having many social resources that are not specific to their individual needs. The participants had several difficulties in essential areas of life, such as family, children, romantic relationships and mental health. The needs of each

caregiver differ between the participants which confirm the necessity of individualised support.[3] Comparing Ensemble to psychoeducational programmes or counselling programme would involve tailoring the support to the need of each participant. The support sessions offer different practical exercises and tools (problem solving, positive communication and assertiveness, involvement as an informed caregiver, emotional support…), which need to be adapted to each participant.

Regarding the primary outcome of the Ensemble pilot study, the participants showed significant improvements in psychological health status as measured by the Global Severity Index (GSI), based on the Brief Symptom Inventory (BSI) scale.[25] After five sessions, the 21 participants' psychological health statuses were improved compared with their pretest scores (pretest mean of the GSI score 0.72 vs post-test GSI score mean 0.53). These findings emphasise that informal caregivers are at greater risk of developing psychological problems than those in nonclinical populations; for example, their mean GSI score pretest (0.72) was higher than that of a healthy British community sample (0.44)[26] and lower than that of a British psychiatric outpatient sample (1.65).[27] Informal caregivers were also more optimistic regarding their future at the end of the programme as a secondary outcome (mean pretest 15.52 vs mean post-test 17.43).

The goal of the current study is to determine whether the Ensemble programme is clinically effective using a randomised, controlled (RCT), and assessor-blinded trial. A combination of Ensemble plus support as usual (SAU) will be compared with SAU alone.

This trial's main hypothesis is that five 1-hour sessions of the Ensemble programme will lead to an improved psychological health state, as evaluated with the GSI score on the BSI scale, compared with those of the control group. The secondary hypothesis is that the Ensemble programme will increase optimism levels as measured on the Life Orientation Test-Revised (LOT-R) scale, improve quality of life as measured by the Short-Form Health Survey (SF-36) scale and decrease the burden score on the Zarit scale. The study will also monitor the sustainability of the potential benefits at follow-up (2 months after completing the Ensemble programme). Qualitative data through 20 semioriented interviews will provide information on outcomes concerning the experience and the added value of the programme for participants at the end of the study.

A study summary according to WHO Trial Registration Data Set items is presented in table 1.

METHODS
Participants, interventions, and outcomes.

Study setting
The study is being conducted in four cantons of French-speaking Switzerland. Informal caregivers providing close support to persons with psychiatric disorders are

Table 1 WHO trial registration data set of ensemble RCT

Data category	Information
Primary registry and trial identifying no	ClinicalTrials.gov: NCT04020497
Date of registration in primary registry	16 July 2019
Secondary identifying numbers	The Federal Office of Public Health's portal for human research in Switzerland NCT04020497 | SNCTP000003434
Source(s) of monetary or material support	Swiss National Science Foundation 10 001C_185422
Primary sponsor	Shyhrete Rexhaj
Secondary sponsor(s)	Jérôme Favrod
Contact for public queries	Shyhrete Rexhaj, s.rexhaj@ecolelasource.ch;+41 21 556 44 35; Avenue Vinet 30; 1004 Lausanne, Vaud, Switzerland
Contact for scientific queries	Shyhrete Rexhaj, PhD, Professor associate
Public title	Programme Ensemble: an early intervention for informal caregivers in psychiatry
Scientific title	Ensemble programme an early intervention for informal caregivers of psychiatric adult patients: a protocol for an RCT Ensemble RCT
Countries of recruitment	Switzerland
Health condition(s) or problem(s) studied	Psychological Distress, quality of life
Intervention(s)	Support as usual (SAU) Informal caregivers often have to manage the situation in various ways. SAU alone consists of informal support by the patient's clinical team. There are specific psychoeducational programmes depending on the patient's illness (such as 'Profamille' for schizophrenia) or peer-support depending to the voluntary work of the families' associations. Some general professional services focused on informal caregivers or relatives in order to inform and orient them if they need are available in the study area. No attempts have been made to standardise this treatment. Ensemble programme plus SAU The five-session Ensemble programme provides targeted support to informal caregivers. It addresses informal caregiver's specific unmet needs, emotions and social resources in order to adapt care activities to each participant.
Key inclusion and exclusion criteria	Inclusion criteria: Being at least 18 years old; living in the French-speaking Switzerland cantons (commonly referred to as 'Romandie') speaking French; having an adult relative suffering from a psychiatric disorder (with or without an established diagnosis); and having the capacity to agree to participate in the project Exclusion criteria: Less than 20 on the Zarit score.
Study type	Interventional
	Allocation: randomised; intervention model: parallel assignment; masking: assessor blind
	Primary purpose: health prevention and promotion
Date of first enrolment	October 2019
Sample sSize	160
Recruitment status	Recruiting
Primary outcome(s)	Psychological state change on the Global Severity Index: Timepoint: Baseline; at post-test, at 2 months follow
Key secondary outcomes	Optimism change on the Life Orientation Test-Revised Time point: Baseline; at post-test, at 2 months follow-up Quality of life change on the Mental Component Score Time point: Baseline; at post-test, at 2 months follow-up Burden level change on the Zarit Burden Interview Timepoint: Baseline; at post-test, at 2 months follow-up Standardised severity of the patient's illness changes on the Social an Occupational Functioning Assessment Scale Time point: Baseline; at 2 months follow-up Qualitative participants' experiences concerning Ensemble benefits and limits
Ethics review	Approved; 28 August 2019; La Commission cantonale d'éthique de la recherche sur l'être humain
Completion date	30 April 2023

RCT, randomised controlled trial.

the target population. 'Informal caregiver', 'caregiver' and 'family caregiver' are terms used to describe family members, friends or significant others who provide this close support. In this area, no systematic or standardised individualised intervention for informal caregivers is implemented. Several sites in these four cantons are informed, and different partners actively support this project (a detailed list can be obtained from the authors) to reflect generalisation issues. The main study site is La Source, School of Nursing Sciences, HES-SO University of Applied Sciences Western Switzerland, Lausanne. However, the research assessments and the meeting intervention can take place at the participants' homes or in other locations defined as appropriate by the participants and intervention providers. The research members will travel up to 3 hours one way for these meetings and assessments.

Eligibility criteria

The study is open to informal caregivers of adult psychiatric patients with a burden score of at least 20 on the French Zarit Burden Interview (ZBI) version scale.[28] This 22-item scale uses a 5-point scale (0 = 'never'; 4 = 'nearly always') to assess the subjective burden (emotional, physical and financial) of an informal caregiver of an individual with a loss of autonomy. The total score can range from 0 to 88. A score less than or equal to 20 indicates a low burden; a score between 21 and 40 indicates a light burden; a score between 41 and 60 indicates a moderate burden; and a score greater than 60 indicates a severe burden. The inclusion criteria for informal caregivers are as follows: being at least 18 years old; living in French-speaking Switzerland; speaking French and having an adult relative suffering from a psychiatric disorder (with or without an established diagnosis). One hundred and sixty participants will be included in this study (n=80 for Ensemble + SAU; n=80 for SAU). In this study, a self-report identification as informal caregivers is selected to offer support to all informal caregivers according to their needs independently of their direct implication in caregiving to patient.

Recruitment

Participants will be recruited from the following family associations in French-speaking Switzerland: l'Îlot (VD), AFS Berne-Neuchâtel (NE), A3 Jura (JU) and APF (FR). Participants will also be recruited at 'l'Espace Proches', which is a nonprofit association created in 2014 and a member of the Department of Health and Social Welfare and the Pallium Foundation. The services of this association are run by health and social professionals and focused on informing, orienting and supporting informal caregivers or relatives. Public mental health services will also be used to recruit participants. Meetings with the presidents of each association and professionals working in mental health services will be organised to present the project. Regular information about the research will be provided at these sites. A recruitment strategy aimed at general practitioners, local newspapers, schools and social and cultural centres, as well as social networks such as Facebook, will be deployed to ensure equivalent treatment among informal caregivers who are isolated or not in contact with any association. Informal caregivers who are willing to participate will choose either to call the research coordinator or give their authorisation to be contacted.

Patient and public involvement

No patient involved.

Interventions

Ensemble programme

Ensemble is a brief individualised intervention designed to promote the well-being of informal caregivers who experience the effects of their patients' psychiatric disorders. It is a five-session programme led by a nurse (who had 2 days of specific training), addressed to the informal caregiver and delivered independent of the patient's treatment. Figure 1 demonstrates the objectives of the Ensemble programme and its process. The five sessions are described and allow the participant to take a step back on her/his informal caregiver's role.

Clinical tools

Three clinical tools are used to specifically assess the needs, difficulties, painful emotions and social networks of the informal caregivers (table 2). These clinical tools are systematic, structured and easy to administer. The three clinical tools selected in the Ensemble programme are (1) the Difficulties and Needs Self-Assessment Tool, (2) the Painful Emotions Tool and (3) the Social Network Tool.[3 25 29 30]

Support as usual

SAU was chosen as a control condition. Informal caregivers must often manage situations in different ways. SAU consists of informal support given by various structures. The patient's clinical team can provide support to the informal caregiver. Specific psychoeducation programmes tailored to the patient's illness (such as 'Profamille' for schizophrenia) are also implemented in the French-speaking Switzerland context. Peer support depends on the voluntary work of family associations. Some general professional services such as 'l'Espace Proches' focus on informing and orienting informal caregivers or relatives in the state of Vaud. No attempts have been made to standardise this treatment as SAU that depends on informal caregivers' needs, knowledge of the health system and their capacity to be in contact with the patient's psychiatric team.

Ensemble programme's implementation

Three nurses are trained to deliver the programme. The training took 2 days and is organised in four sessions.

Session 1: issues concerning support for family caregivers, theoretical foundations of the Ensemble
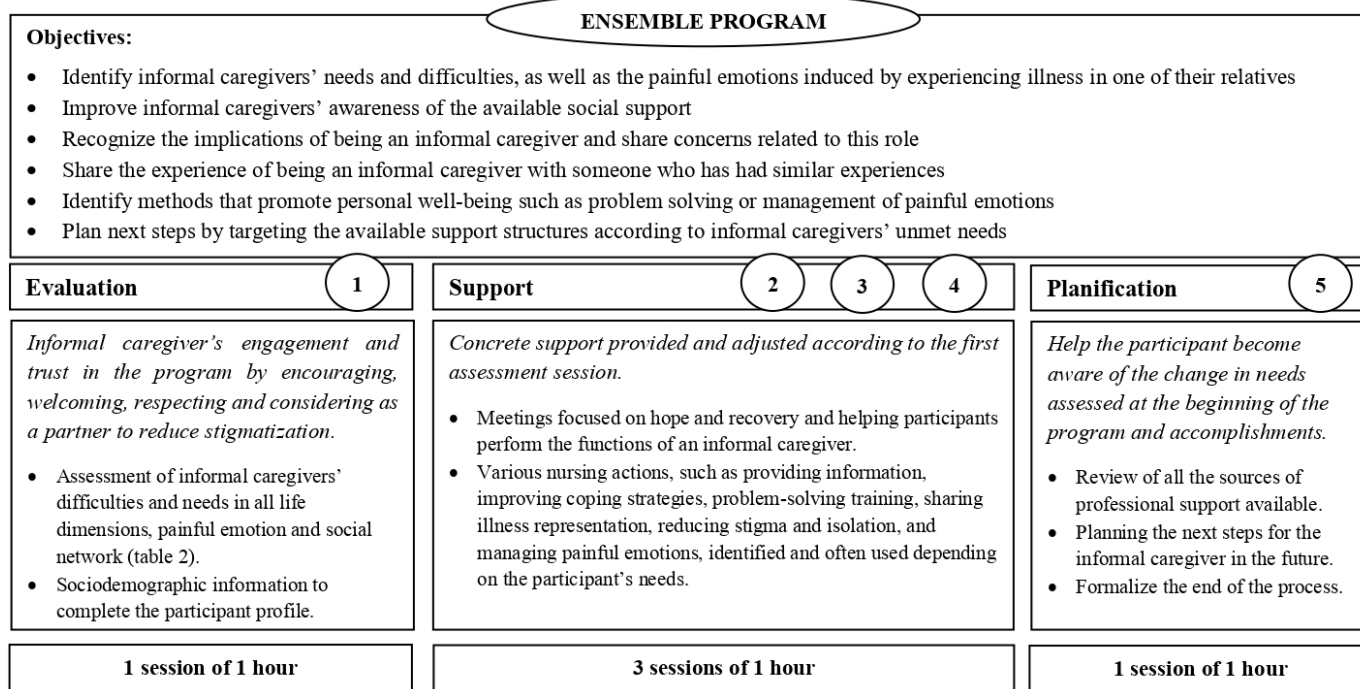
ENSEMBLE PROGRAM

Objectives:

- Identify informal caregivers' needs and difficulties, as well as the painful emotions induced by experiencing illness in one of their relatives
- Improve informal caregivers' awareness of the available social support
- Recognize the implications of being an informal caregiver and share concerns related to this role
- Share the experience of being an informal caregiver with someone who has had similar experiences
- Identify methods that promote personal well-being such as problem solving or management of painful emotions
- Plan next steps by targeting the available support structures according to informal caregivers' unmet needs

Evaluation (1)

Informal caregiver's engagement and trust in the program by encouraging, welcoming, respecting and considering as a partner to reduce stigmatization.

- Assessment of informal caregivers' difficulties and needs in all life dimensions, painful emotion and social network (table 2).
- Sociodemographic information to complete the participant profile.

1 session of 1 hour

Support (2) (3) (4)

Concrete support provided and adjusted according to the first assessment session.

- Meetings focused on hope and recovery and helping participants perform the functions of an informal caregiver.
- Various nursing actions, such as providing information, improving coping strategies, problem-solving training, sharing illness representation, reducing stigma and isolation, and managing painful emotions, identified and often used depending on the participant's needs.

3 sessions of 1 hour

Planification (5)

Help the participant become aware of the change in needs assessed at the beginning of the program and accomplishments.

- Review of all the sources of professional support available.
- Planning the next steps for the informal caregiver in the future.
- Formalize the end of the process.

1 session of 1 hour

Figure 1 Ensemble programme and process.

programme, professional posture and informal caregivers' health considerations.

Session 2: Ensemble Programme: tailored support, structured and individualised process, assessment of difficulties and needs, painful emotions and social resources, practical training to use the clinical tools with a vignette designed from the pilot phase, issues concerning the awareness of the informal caregiver's role.

Session 3: Practical exercises of the support tools—problem solving, positive communication and assertiveness, and involvement as an informed caregiver.

Sessions 4: Practical exercises of the support tools—emotional support, isolation and peer support, and referral to appropriate structures.

In addition to this training, nurses received a manual protocol and are supervised for every clinical situation. To ensure the standardisation on delivery, two supervisions moments are planned: the first after the first meeting between the nurse and the participants and the second before their last meeting. The place for delivery of the sessions are in a private and quiet room located to the nursing school, or in a clinical local or in the participant's home. Sometime if the participant prefers the delivery could take place in the 'tea-room or hotel' but this option is retained only if the other options are not suitable for the participant.

Outcomes

Quantitative data gathered through various standard instruments will inform the main and secondary outcomes. Table 3 summarises the expected results.

Qualitative data will also inform some secondary outcomes. Content analysis will focus on not only informal caregivers' experiences but also their capacity to manage the situation. To narrate their experiences and construct meaning through heuristic narrative processes,[31] the analysis of the categorisation devices used by the participants will provide us with comprehensive insight into the types of experiences during the programme, different capacities and unmet needs.

Table 2 Clinical tools

Clinical tools	Description
The Difficulties and Needs Self-Assessment Tool (ELADEB)	The ELADEB includes two independent scales, one focusing on difficulties and the other focusing on support for unmet needs. Twenty-one areas of life that enable identification of priority problems and orientation of support according to the level of emergency are assessed. These 21 areas of life are organised into four life dimensions: life conditions, daily pragmatic activities, relationships and health.
The Painful Emotions Tool	It uses pictures that reflect painful emotions such as guilt, judgement from others, loneliness, sadness, distress, despair, anxiety, helplessness, anger, confusion and shame. The participant selects the painful emotions that are present in his/her life. The tool also assesses the frequency of the emotions. Consequently, the support provided is targeted to the caregiver's most painful emotions.
The Social Network Tool	It uses a network map that specifies the social resources available to the caregiver. This tool provides a graphic representation aimed at identifying the informal caregiver's primary, secondary and tertiary environment.

Table 3 Expected quantitative results

Outcome	Question	Data	Analysis	Expected result
Main	Is the psychological state improved?	Global Severity Index on the Brief Symptom Inventory	ANCOVA of T1-T0, T2-T0, T0 as dependent, treatment condition as fixed factor	Experimental group statistically and clinically significantly improved compared with SAU
Secondary	Is optimism improved?	Life Orientation Test-Revised	ANCOVA of T1-T0, T2-T0, T0 as dependent, treatment condition as fixed factor	Experimental group statistically and clinically significantly improved compared with SAU
	Is quality of life improved?	36-item Medical Outcome Study Short-Form Health Survey-Mental Component Score	ANCOVA of T1-T0, T2-T0, T0 as dependent, treatment condition as fixed factor	Experimental group statistically and clinically significantly improved compared with SAU
	Is the burden reduced?	Zarit Burden Interview	ANCOVA of T1-T0, T2-T0, T0 as dependent, treatment condition as fixed factor	Experimental group statistically and clinically showed significant reduction compared with SAU
	Is the patient's social and occupational function improved?	Social and Occupational Functioning Assessment Scale	ANCOVA of T0-T2, T0 as dependent, treatment condition as fixed factor	Experimental group statistically reported improvements for patients compared with SAU

ANCOVA, analysis of covariance; SAU, support as usual.

Sample size

The sample size was estimated using the results of the pilot study regarding the main outcome of the expected BSI Global Index. For the sample size calculation, α was set at 0.05 with a power of β=0.80. The effect size of the expected difference between the two groups was equal to Cohen's d=0.470. Using an a priori computation for analysis of covariance (ANCOVA), the proposed trial required a total sample size of 144 participants for the two arms, 72 in each arm. In the pilot study, 1 of 22 participants dropped out, resulting in a dropout rate of approximately 5%; to increase security in the proposed study, a drop-up rate of 10% will be considered, corresponding to a dropout number of 22 participants, so the present study will recruit 160 participants. Between-group differences in pretest and post-test values will be examined using ANCOVA.

Participant timeline and RCT process

Figure 2 shows the clear and synthetic timeline of participant interactions and this RCT process.

Allocation

The Research Electronic Data Capture (REDCap) platform will be used to randomise the participants. REDCap is a secure, web-based application designed to support data capture for research studies. It developed a module that allows a defined randomisation model be implemented within the project. The randomisation by group/ site model was defined. A randomisation table was created by the data manager and imported to the project database to structure the allocation. REDCap will randomise the participants according to this table, which is not available to the research team. A total of 180 assignments in the allocation table were included to accommodate possible drop-outs and additional enrolment of participants.

A person not involved in the execution of the project will confirm that the eligibility data are complete in order to proceed with the randomisation. She/he will then inform the intervention provider of the allocated arm.

The intervention provider will inform the participants whether they are in the intervention arm, but the assessor will not be informed of hers/his treatment group allocation.

The role of the assessor is to ensure the connection to the REDCap platform that holds the research questionnaires. The assessor responds to eventual questions about item understandings during the assessment. The assessor is blind and reminds the participant not to communicate hers/his treatment group allocation at the beginning of every encounter at T1 and T2. The assessor will also collaborate with one of the investigators at the end of the study to collect qualitative data.

The research assistants will alternatively play the role of either the assessor or the intervention provider to diversify their work and develop specific competences related to each role. To maintain blindness of assessment, several conditions have been set: one assistant researcher will take the role of assessor for the first five participants before providing the intervention for the next five. Another assistant researcher will do the opposite and so on. If a leak of allocation occurs, this information will be noted, and analyses concerning the eventual impacts will be conducted. However, all standardised questionnaires are basically self-administered.

The interventions will take place in a building other than the assistants' office. The supervision between interventions will be individualised and organised by one of the two lead investigators.

Data collection, management and analysis

Study data will be collected and managed using REDCap electronic data capture tools hosted at HES-SO Fribourg. REDCap provides (1) an intuitive interface for validated data entry; (2) audit trails for tracking data manipulation
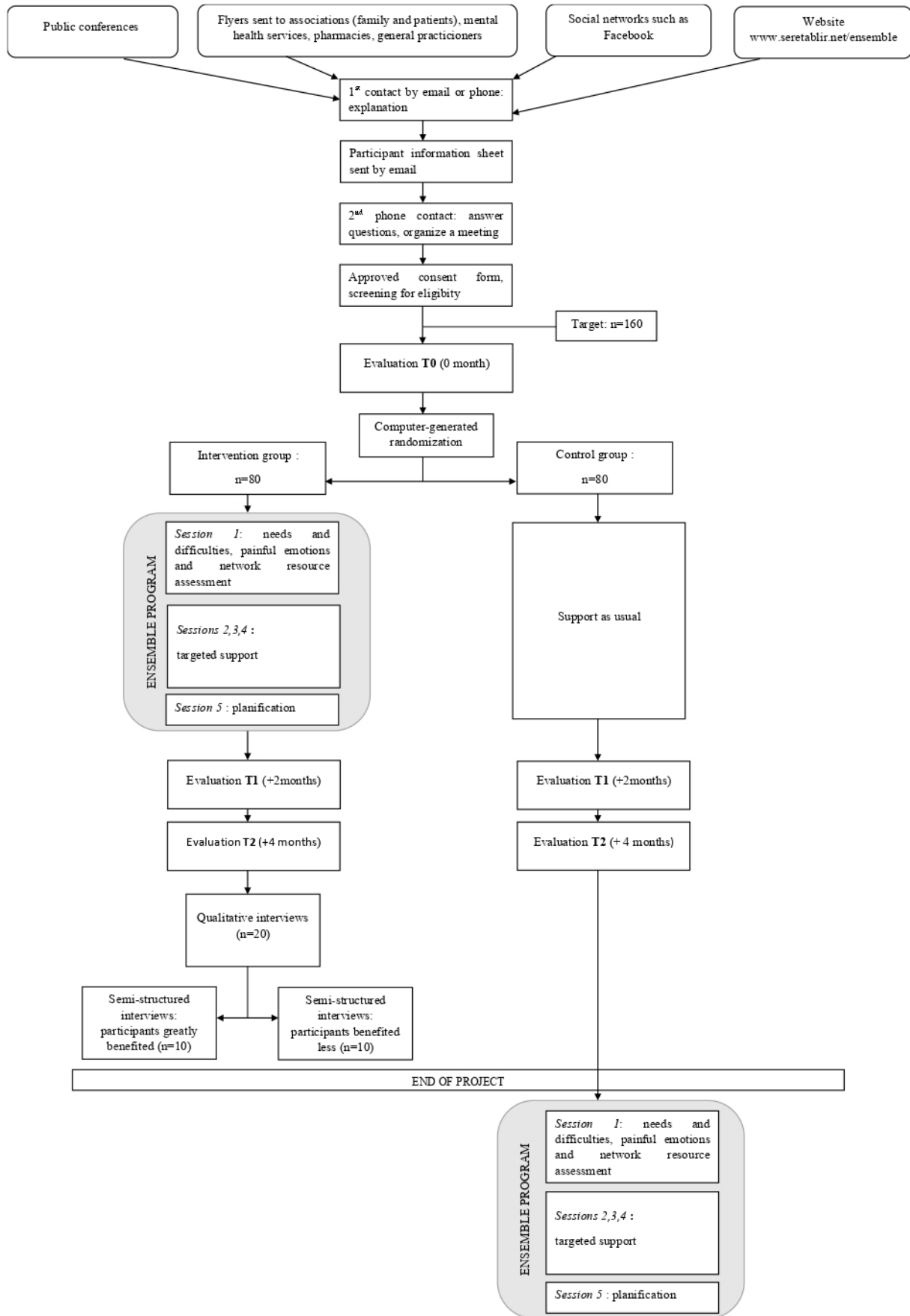
Figure 2 RCT flow chart. RCT, randomised controlled trial.

Table 4 Ensemble risk reduction protocol schedule of assessments and procedures

Procedures/assessments	CRF (yes/no)	Staff member	Time (min)	−1 Screening/ consent	T0 Baseline/ randomisation	First and second month Ensemble versus support as usual	T1 Post-test	T2 Follow-up 4 months
Oral and written information	No	Research collaborator	20	√				
Consent	No	Research collaborator	30	√				
Eligibility criteria assessment	Yes	Research collaborator	10		√			
Sociodemographic questionnaire	Yes	Assessor			√			
The French Zarit Burden Interview	Yes	Assessor			√		√	√
Randomisation-computer generated	Yes	A specific randomisation coordinator	10		√			
The Brief Symptom Inventory	Yes	Assessor			√		√	√
The Life Orientation Test-Revised	Yes	Assessor			√		√	√
The 36-item Medical Outcome Study Short-Form Health Survey	Yes	Assessor			√		√	√
The Social and Occupational Functioning Assessment Scale	Yes	Assessor			√			√
Qualitative data by 20 semi-directed interviews with participants in intervention	No	Two research collaborators						√
Treatment group	Yes	Intervention provider	360			√		
All groups, being in touch and continuing information	No	Intervention provider	30			√		
Supervision of intervention provider	No	Study coordinator	According to need	Continuously				
Termination of the study		Study coordinator	According to need	Continuously				
Serious adverse event form		Study coordinator	According to need	Continuously				
Progress notes	No	All team members	According to need	Continuously				

and export procedures; (3) automated export procedures for seamless data downloads to common statistical packages and (4) procedures for importing data from external sources.

Primary outcome

The BSI aims to assess psychological symptoms and psychological distress. It includes 53 items organised into 9 primary and clinically relevant symptom dimensions: (1) somatisation; (2) obsessive–compulsive; (3) interpersonal sensitivity; (4) depression; (5) anxiety; (6) hostility; (7) phobic anxiety; (8) paranoid ideation and (9) psychoticism.[32] This scale also has three global distress indices: the GSI, the Positive Symptom Distress Index and the Positive Symptom Total. The BSI scale has been used in a variety of clinical and counselling settings as a screening tool for mental disorders and as a method of measuring symptom reduction.[33–36] It has also been used to assess the psychological health status of informal caregivers.[25 37 38] The GSI of the BSI scale was used as one of the main outcome measures in the pilot study and represents the mean of the nine primary symptom dimensions and is more sensitive than the two other global indices.[32] Higher GSI scores indicate a greater effect on informal caregivers' psychological health. The validation of the French BSI scale indicated good internal consistency for the GSI score ($\alpha=0.91$).[39]

Secondary outcomes

The French ZBI includes 22 items to assess the subjective burden (emotional, physical and financial) of an informal

caregiver of an individual with a loss of autonomy.[28] The total score can range from 0 to 88. A score less than or equal to 20 indicates a low burden; a score between 21 and 40 indicates a light burden; a score between 41 and 60 indicates a moderate burden and a score greater than 60 indicates a severe burden. This questionnaire has been mainly used for chronic illnesses such as dementia, palliative care or mental disorders.[40–42]

The LOT-R developed by Scheier et al[43] measures an individual's optimism regarding a given situation. This self-administered scale measures the adaptive strategies correlated with well-being and is used to evaluate optimism vs pessimism. The LOT-R has been translated and validated in French, with good psychometric proprieties (internal consistency α=0.76).[44] The scale includes 10 items: three items measure optimism, three others measure pessimism and four items function as fillers. The participants respond to each item on a 5-point Likert scale ranging from 0 (strongly disagree) to 4 (strongly agree); the four filler items are not included in the total score calculation. Higher scores suggest more optimism. Optimism has been shown to be negatively correlated with distress[45 46] and to positively influence quality of life.[47] Among informal caregivers in particular, optimism promotes engagement in supportive programmes,[48] whereas pessimism leads to the use of avoidance strategies, which can predict informal caregiver burden.[49]

The 36-item Medical Outcome Study SF-36 developed by Ware and Sherbourne[50] measures some health indicators related to quality of life. It includes 36 items and is used in clinical and general population settings to evaluate eight health dimensions: physical functioning, bodily pain, role limitations due to physical health problems, role limitations due to personal or emotional problems, emotional well-being, social functioning, energy/fatigue and general health perceptions. Two global scores— (1) a Physical Component Score and (2) the Mental Component Score – are obtained by grouping the eight dimensions, and these two synthetic variables allow different populations to be compared. The French version of the SF-36 was validated by obtaining Cronbach's (reliability) coefficients ranging from 0.76 to 0.92.[51–54] In clinical settings, this type of measure can also help professionals orient informal caregivers towards a targeted intervention.[55 56]

The different standard measures will be used in the three standard evaluations (T0=pretest; T1=post-test at an average of 2 months and T2=follow-up at an average of 4–5 months). A research assistant trained to answer technical questions will be present during the questionnaire's completion.

The Social and Occupational Functioning Assessment Scale (SOFAS) developed by Goldman et al[57] is used in order to reflect the severity of the patient's illness in the professional and social functioning. This scale does not consider the psychiatric symptoms' severity. It is a continuous scale (0–100) which present 10 functioning level, each level is described by a short text. A higher level (91 to 100) shows a more superior social and occupational functioning. This scale is validated in French (coefficients ranging from 0.61 to 0.91) and largely used in clinical context and different research projects.[58–60] The SOFAS will be administered at T2 to compare eventual improvements by the patient according to the informal caregiver and explore differences in informal caregivers' outcomes.

Sociodemographic data will be collected at T0: sex, age, education level, professional activity, the nature of their relationship with the patient, whether they live with the patient, the number of close contacts and previous requests for help. Information about the patient will complete the sociodemographic data: the patient's sex, age, diagnosis according to the caregivers and its duration. No medical data about the patient will be collected which limits the medical diagnosis specification. However, analyses by diagnostic group according to the informal caregiver and the SOFAS level will be done in order to explore differences between groups.

The Satisfaction Scale concerning the Ensemble programme was developed and used in the pilot study.[25] This scale will be used only in the post-test evaluation of the intervention group to show the participants' satisfaction.

The aim of the qualitative part of this project is to conduct a qualitative open and exploratory study. Qualitative data will be collected through semidirective interviews. They will aim to provide significant information regarding participant experiences in the programme (capacities to manage painful emotions and difficulties worked on during the programme and to have and increase awareness of the informal caregiver's role). Participants will be able to express their views about both advantages and disadvantages of the intervention, and the impacts in the quality of life.

Semidirective interviews will be conducted at the end of the study with 20 selected participants to explore their experiences participating in the Ensemble programme. These participants will be selected at the end of the intervention in the intervention arm. Two groups of participants will be included in this phase: those who have benefited greatly from the programme (G1; n=10) and those who have benefited less (G2; n=10). At the end of the quantitative part for all participants, the 80 subjects will be separated in two groups: those who have a better score and those who have a poorer score in the main outcome (BSI score) in T1 compare to T0. Then for each group, 10 participants will randomly be selected and be contacted for participating in the qualitative study.

This stratification of the sample will allow us to better understand the added value of the Ensemble programme and to identify areas for improvement. The process for this step occurs in two phases: (1) the participant receives information at the time of recruitment and agrees to participate (not only in the project itself but also to the semi-directive interview) and (2) the research team contacts the participants who have consented. Detailed information and conditions will then be given. The

Table 5 Interview guide for the qualitative open and exploratory study relative to caregiver's experiences during the Ensemble programme

Introduction

Acknowledgments and facilitator presentation: First, I would like to thank you for accepting this interview. It will allow us to explore your experience during the Ensemble programme. I would like you to share with me your experience, feelings, advantages and disadvantages that occurred during your participation in this programme. I am, Name and Surname. I am speaking as a researcher. I was not involved in the Ensemble project until now. I work at La Source, School of nursing, University of Applied sciences and Arts Western Switzerland, in Lausanne. I am very pleased to meet you this morning/afternoon.
Purpose of the interview: As the project investigators have already told you, the purpose of this interview is to understand, in a qualitative way, your Ensemble programme experience. Interview procedure: The interview should last about 1 hour maximum. Confidentiality: I guarantee you that the content of our exchange will only be used for scientific research purposes and that your identity will remain confidential. The analyses will focus on the content of this interview and the results of the questionnaires that you have filled in during the first step of the project. There will be no way to identify your personal data is coded. Audio recording: If it is ok with you, as written in the consent sheet/form, I would like to record the interview, in order to make our note-taking easier and so allow me to focus on our conversation. The recordings will not be in any case diffused nor shared outside the project's team. Participant's comfort: Is everything ok for you? Do you have any question before we start?

Interview	Objectives
Interview opening question: Can you describe me your experience during the Ensemble programme? Questions to ask in order to sustain and revive the speech of the participant: How would you qualify the help that you have received during the Ensemble programme? What advantages for you and your relative, have you identified in this programme? What disadvantages for you and your relative, have you identified in this programme? Which contents/exercises have helped you to better manage your situation or your caregiver role? On the contrary, which contents/exercises have you found pointless? What do you think of the term « caregiver »? Has the Ensemble programme eventually contributed to better assimilate this notion or on the contrary, to reject it? Explain. What remarks or suggestions would you give to improve the support that you have received? Is your situation different after the intervention compared with your situation before? Yes/No; How different is your situation? If Yes, do you attribute this difference to your participation in the Ensemble programme? Which elements of the programme seem to have played a part in this change of your situation/life? Which elements of the programme seem to have helped to initiate that change? Is your relative health state different after this intervention (compared with what it was before)? Yes/No; How different is the state of health of your relative? Do you think that this improvement/change is related to the support that you have received? Yes/No; If Yes, how do you explain this relation between improvement/change and the Ensemble programme Which impacts have you noticed in your quality of life? Could you tell me a major situation that you might have experienced during the Ensemble programme? What was useful during the accompaniment? What more would you have liked? What do you considerate as not enough nor not useful? How would you qualify the relationship that you have had with the intervention provider of the Ensemble programme?	To understand the Ensemble programme experience of the participant in general. To identify: (1) the eventual benefits and disadvantages of the Ensemble programme for the caregiver and his/her relative, (2) the contribution of the contents and practical exercises of the programme in the capacity to manage painful emotions and resolve difficulties during the programme, or in the future, (3) the contribution of the programme on the empowerment in the caregiving role or for the person independently of this role, (4) indications in order to improve the programme. To observe the eventual process of change (quality of life, situation…) that the programme might have generated. To get concrete illustrations of these changes and information on the accompaniment of the intervention provider.

Conclusion

In the end, what « word » would you choose to qualify/describe your experience as a participant in this programme? Would you like to add anything?	To propose a review and offer possibility to add anything.

participants will have time to read the conditions and think about their participation in this research step. At the time of the interview, before starting the interview and its audio recording, a few minutes will be dedicated to potential questions about the information and consent form or other interrogations. Qualitative data collection will thus constitute both an autonomous inquiry and an opportunity to enrich data obtained through standardised questionnaires.[61] Participants will be able to express their views about both advantages and disadvantages of the intervention, and the impacts in the quality of life. In order to ensure that the participant feels free in sharing her/his experiences and challenges, a researcher not involved in the project realisation will conduct these qualitative interviews.

Finally, all standardised questionnaires will be checked at the end of each assessment meeting for the presence of missing data and to reach agreement about how to complete these missing data.

Table 4 presents the plan to retain participants and the completed list of the collected data.

Analysis

Primary analyses will be conducted on an intent-to-treat basis. To ensure the statistical analyses, a researcher responsible for the analysis will be involved. He/she will double control the final quantitative data before analyses and check the different tests. The following analyses are planned: between-group differences in pretest and post-test values will be examined using an ANCOVA for each outcome variable for the quantitative data. Differences between pretest and post-test scores, as well as between pretest and follow-up scores, will be treated as dependent variables; treatment conditions will be treated as a fixed factor, and pretreatment scores will be treated as covariates. Between-subjects Cohen's d effect sizes will be calculated at post-test and follow-up. For within subjects, Cohen's d will be calculated between the pretest and post-test and between the pretest and follow-up, correcting for dependence among means.

The content analysis of the qualitative data will focus on informal caregivers' experiences in general, as well as their capacity to manage situations. The aim of this analysis is to provide us with a participant's comprehensive insight into the types of experiences (positive or negative) during the programme, their different capacities and unmet needs. The interview guide (table 5) permits to better show all elements that will be explored during the qualitative study. A content analysis will be provided for each part of the follow-up questions.

Monitoring

Data will be accessible to the investigators and the research assistants during the project. The REDCap platform will control this accessibility. Relevant data will be accessible by a login password to only staff members of this project depending on their responsibilities. For example, an assistant scientific researcher involved in the randomisation phase will only access these data. The data set will be controlled by investigators and transferred to 25 SPSS software before the final analyses. The investigators using the REDCap platform will ensure the traceability of the data and present all the aspects to the audit trial member.

A person external to the project and the institution will audit the data and the project process once a year. She/he will perform the following functions:

► Consent checks (100%).
► Verification of raw data (first participant all data; for the other participants several randomly selected data).
► Verification of Case Report Form (CRF) completeness and consistency: data consistency, data reconciliation, data cleaning, generation of subsequent queries, data derivation, data set formatting prior to statistical analysis, table shells, depersonalisation and anonymisation.

Ethics and dissemination

The research protocol received full authorisation from the Human Research Ethics Committee of the Vaud State, Switzerland. Participants will be informed about the study and their rights and sign a written informed consent form (see online supplementary file: Information et consent_Ensemble). All data will be archived for 10 years after study termination or premature termination of the study. The data pertaining to the hypothesis will be mostly published in open access journals. After priority publications, metadata following Findability, Accessibility, Interoperability and Reuse (FAIR) recommendations will be accessible on the FORSbase platform to allow other researchers to access these data, to proceed with other secondary analyses and to enrich research. This trusted platform offers the possibility of archiving and ensuring the long-term visibility and preservation of the data. Access to the data files will be granted only to researchers external to the project who meet the criteria required by FORSbase.

Adverse event management

Informal caregivers could present painful emotions and could need care for their own health conditions at the beginning of the project and during it. Ethical recommendations allow for those experiencing such adverse events to be enrolled, as they present significant symptoms that are not immediately life-threatening.[62] The principal investigators will be informed within 24 hours and will assess the severity of the event as mild, moderate or severe. Mild complications are tolerable, moderate complications interfere with daily activities, and severe complications render daily activities impossible. If a severe adverse event occurs according to Art. 63,[62] the research project will be interrupted and the ethics committee will be notified about the circumstances within 15 days according to Human Research Ordinance (HRO) Art. 212.[62] Only one severe adverse event not related to the research project occurred during the pilot study. The participant decided merely to stop the project to have time for individual care related to advanced cancer. The informed consent materials and information sheets given to participants are available in French and English through the following website: https://www.seretablir.net/ensemble/

the principal investigator, is responsible for ethical considerations (providing an annual risk report to the ethics committee, providing information on serious adverse events, and announcing any change in the protocol if necessary) and for the study procedures (management of the team and responsible for the data file and budget administration). Noémie Laverne, who was not involved in the execution of the project, is responsible for randomisation even for participants who were randomly by computer, as the computer system requires oversight.The data manager Anne-Laure Kauffman maintains the trial IT system using the REDCap platform and will audit all procedures of the study once a year.

ORCID iDs
Shyhrete Rexhaj http://orcid.org/0000-0003-1149-6470
Shadya Monteiro http://orcid.org/0000-0002-5569-4105
Philippe Golay http://orcid.org/0000-0002-2273-6241
Claire Coloni-Terrapon http://orcid.org/0000-0002-4793-1801
Daniel Wenger http://orcid.org/0000-0001-9951-5466
Jérôme Favrod http://orcid.org/0000-0002-1132-9472

REFERENCES

1. Rexhaj S, Python NV, Morin D, *et al*. Correlational study: illness representations and coping styles in caregivers for individuals with schizophrenia. *Ann Gen Psychiatry* 2013;12:27.
2. Bonsack C, Rexhaj S, Favrod J, *et al*. Psychoéducation: définition, historique, intérêt et limites. *Annales Médico-psychologiques, revue psychiatrique* 2015;173:79–84.
3. Rexhaj S, Leclerc C, Bonsack C, *et al*. Approche pour cibler Le soutien auprès des proches aidants de personnes souffrant de troubles psychiatriques sévères. *Annales Médico-psychologiques, revue psychiatrique* 2017;175:781–7.
4. Lobban F, Glentworth D, Haddock G, *et al*. The views of relatives of young people with psychosis on how to design a relatives education and coping toolkit (react). *J Ment Health* 2011;20:567–79.
5. Corcoran C, Gerson R, Sills-Shahar R, *et al*. Trajectory to a first episode of psychosis: a qualitative research study with families. *Early Interv Psychiatry* 2007;1:308–15.
6. Lucksted A, McFarlane W, Downing D, *et al*. Recent developments in family psychoeducation as an evidence-based practice. *J Marital Fam Ther* 2012;38:101–21.
7. Möller-Leimkühler AM. Multivariate prediction of relatives' stress outcome one year after first hospitalization of schizophrenic and depressed patients. *Eur Arch Psychiatry Clin Neurosci* 2006;256:122–30.
8. Andresen R, Caputi P, Oades L. Stages of recovery instrument: development of a measure of recovery from serious mental illness. *Aust N Z J Psychiatry* 2006;40:972–80.
9. Coloni-Terrapon C, Favrod J, Clément-Perritaz A, *et al*. Optimism and the psychological recovery process among informal caregivers of inpatients suffering from depressive disorder: a descriptive exploratory study. *Front Psychiatry* 2019;10:972.
10. Dallaire C, Toupin I. Les théories spectre modéré, les théories propres aux situations et les interventions infirmières. In: Dallaire IC, ed. *Le SAVOIR infirmier: Au coeur de la discipline et de la profession infirmière*. Boucherville: Gaëtan Morin, 2008: 239–64.
11. Lobban F, Glentworth D, Chapman L, *et al*. Feasibility of a supported self-management intervention for relatives of people with recent-onset psychosis: react study. *Br J Psychiatry* 2013;203:366–72.
12. Lobban F, Postlethwaite A, Glentworth D, *et al*. A systematic review of randomised controlled trials of interventions reporting outcomes for relatives of people with psychosis. *Clin Psychol Rev* 2013;33:372–82.
13. Sin J, Moone N, Wellman N. Developing services for the carers of young adults with early-onset psychosis--listening to their experiences and needs. *J Psychiatr Ment Health Nurs* 2005;12:589–97.
14. Magaña SM, Ramírez García JI, Hernández MG, *et al*. Psychological distress among Latino family caregivers of adults with schizophrenia: the roles of burden and stigma. *Psychiatr Serv* 2007;58:378–84.
15. Bauer R, Koepke F, Sterzinger L, *et al*. Burden, rewards, and coping--the ups and downs of caregivers of people with mental illness. *J Nerv Ment Dis* 2012;200:928–34.
16. Möller-Leimkühler AM. Burden of relatives and predictors of burden. baseline results from the Munich 5-year-follow-up study on relatives of first hospitalized patients with schizophrenia or depression. *Eur Arch Psychiatry Clin Neurosci* 2005;255:223–31.
17. van der Voort TYG, Goossens PJJ, van der Bijl JJ. Alone together: a grounded theory study of experienced burden, coping, and support needs of spouses of persons with a bipolar disorder. *Int J Ment Health Nurs* 2009;18:434–43.
18. Rexhaj S, Jose AE, Golay P, *et al*. Perceptions of schizophrenia and coping styles in caregivers: comparison between India and Switzerland. *J Psychiatr Ment Health Nurs* 2016;23:585–94.
19. Plessis L, Golay P, Wilquin H, *et al*. Internal validity of the French version of the family coping questionnaire (FCQ): a confirmatory factor analysis. *Psychiatry Res* 2018;269:337–44.
20. Pilling S, Bebbington P, Kuipers E, *et al*. Psychological treatments in schizophrenia: I. meta-analysis of family intervention and cognitive behaviour therapy. *Psychol Med* 2002;32:763–82.
21. Khazaal Y, Richard C, Preisig M, *et al*. Psychoéducation des proches de patients bipolaires : impact sur les patients. Rationnel, développements et perspectives. *Revue Médicale Suisse* 2004;504.
22. Shimazu K, Shimodera S, Mino Y, *et al*. Family psychoeducation for major depression: randomised controlled trial. *Br J Psychiatry* 2011;198:385–90.
23. Gavois H, Paulsson G, Fridlund B. Mental health professional support in families with a member suffering from severe mental illness: a grounded theory model. *Scand J Caring Sci* 2006;20:102–9.
24. Murray-Swank A, Dixon LB, Stewart B. Practical interview strategies for building an alliance with the families of patients who have severe mental illness. *Psychiatr Clin North Am* 2007;30:167–80.
25. Rexhaj S, Leclerc C, Bonsack C, *et al*. Feasibility and accessibility of a tailored intervention for informal caregivers of people with severe psychiatric disorders: a pilot study. *Front Psychiatry* 2017;8:178.
26. Francis VM, Rajan P, Turner N. British community norms for the brief symptom inventory. *Br J Clin Psychol* 1990;29:115–6.
27. Ryan C. British outpatient norms for the brief symptom inventory. *Psychol Psychother* 2007;80:183–91.
28. Hébert R, Bravo G, Girouard D. Fidélité de la traduction Française de trois instruments d'évaluation des aidants naturels de malades déments. *Can J Aging* 1993;12:324–37.
29. Bellier-Teichmann T, Golay P, Bonsack C, *et al*. Patients' needs for care in public mental health: unity and diversity of Self-Assessed needs for care. *Front Public Health* 2016;4:22.
30. Ferrari P. Transition et rétablissement. *Santé Mentale* 2012;166:58–63.
31. Bruner J. *Life as narrative. social research*, 1987: 11–32.
32. Derogatis LR, Melisaratos N. The brief symptom inventory: an introductory report. *Psychol Med* 1983;13:595–605.
33. Grassi L, Johansen C, Annunziata MA, *et al*. Screening for distress in cancer patients: a multicenter, nationwide study in Italy. *Cancer* 2013;119:1714–21.
34. Burstein M, Stanger C, Dumenci L. Relations between parent psychopathology, family functioning, and adolescent problems in substance-abusing families: disaggregating the effects of parent gender. *Child Psychiatry Hum Dev* 2012;43:631–47.
35. Shacham E, Reece M, Ong'or WO, *et al*. A cross-cultural comparison of psychological distress among individuals living with HIV in Atlanta, Georgia, and Eldoret, Kenya. *J Int Assoc Physicians AIDS Care* 2010;9:162–9.
36. Senecky Y, Agassi H, Inbar D, *et al*. Post-adoption depression among adoptive mothers. *J Affect Disord* 2009;115:62–8.
37. Razani J, Kakos B, Orieta-Barbalace C, *et al*. Predicting caregiver burden from daily functional abilities of patients with mild dementia. *J Am Geriatr Soc* 2007;55:1415–20.
38. Neil E. The mental distress of the birth relatives of adopted children: 'disease' or 'unease'? Findings from a UK study. *Health Soc Care Community* 2013;21:191–9.
39. Fortin MF, Coutu-Wakulczyk G. *Validation et Normalisation d'une Mesure de Santé Mentale: le SCL-90-R. [Rapport présenté au Conseil québécois de la recherche sociale (CQRS*, 1985.
40. Martín-Carrasco M, Fernández-Catalina P, Domínguez-Panchón AI, *et al*. A randomized trial to assess the efficacy of a psychoeducational intervention on caregiver burden in schizophrenia. *Eur Psychiatry* 2016;33:9–17.

41 Gonçalves-Pereira M, Zarit SH. The Zarit burden interview in Portugal: validity and recommendations in dementia and palliative care. *Acta Med Port* 2014;27:163–5.

42 Chien WT, Lee YM. A disease management program for families of persons in Hong Kong with dementia. *Psychiatr Serv* 2008;59:433–6.

43 Scheier MF, Carver CS, Bridges MW. Distinguishing optimism from neuroticism (and trait anxiety, self-mastery, and self-esteem): a reevaluation of the life orientation test. *J Pers Soc Psychol* 1994;67:1063–78.

44 Trottier C, Mageau G, Trudel P, *et al*. Validation de la version canadienne-française Du life orientation Test-Revised. *Can J Behav Sci* 2008;40:238–43.

45 Carver CS, Pozo C, Harris SD, *et al*. How coping mediates the effect of optimism on distress: a study of women with early stage breast cancer. *J Pers Soc Psychol* 1993;65:375–90.

46 Carver CS, Pozo-Kaderman C, Harris SD, *et al*. Optimism versus pessimism predicts the quality of women's adjustment to early stage breast cancer. *Cancer* 1994;73:1213–20.

47 Schou I, Ekeberg Ø, Ruland CM. The mediating role of appraisal and coping in the relationship between optimism-pessimism and quality of life. *Psychooncology* 2005;14:718–27.

48 Chien WT, Chan S, Morrissey J, *et al*. Effectiveness of a mutual support group for families of patients with schizophrenia. *J Adv Nurs* 2005;51:595–608.

49 Cotton SM, McCann TV, Gleeson JF, *et al*. Coping strategies in carers of young people with a first episode of psychosis. *Schizophr Res* 2013;146:118–24.

50 Ware JE, Sherbourne CD. The mos 36-item short-form health survey (SF-36). I. conceptual framework and item selection. *Med Care* 1992;30:473–83.

51 Leplegue A, Mesbah M, Marquis P. Analyse préliminaire des propriétés psychométriques de la version Française d'un questionnaire international de mesure de qualité de vie: Le mos SF-36 (versions 1.1). *Revue d'épidémiologie et de santé publique* 1995;43:371–9.

52 Perneger TV, Leplège A, Etter JF, *et al*. Validation of a French-language version of the mos 36-Item short form health survey (SF-36) in young healthy adults. *J Clin Epidemiol* 1995;48:1051–60.

53 Richard JL, Bouzourène K, Gallant S, *et al*. *Validation et normes Du SF-36 dans La population Du Canton de Vaud*. Lausanne Institut Universitaire de médecine sociale et préventive Raisons de santé 28, 2000.

54 Leplège A, Ecosse E, Verdier A, *et al*. The French SF-36 health survey: translation, cultural adaptation and preliminary psychometric evaluation. *J Clin Epidemiol* 1998;51:1013–23.

55 Fekete C, Tough H, Siegrist J, *et al*. Health impact of objective burden, subjective burden and positive aspects of caregiving: an observational study among caregivers in Switzerland. *BMJ Open* 2017;7:e017369.

56 Boyer L, Baumstarck K, Alessandrini M, *et al*. Emotional intelligence and coping strategies as determinants of quality of life in depressed patient-caregiver dyads: an actor-partner interdependence analysis. *Compr Psychiatry* 2017;74:70–9.

57 Goldman HH, Skodol AE, Lave TR. Revising axis V for DSM-IV: a review of measures of social functioning. *Am J Psychiatry* 1992;149:9.

58 Oppetit A, Bourgin J, Martinez G, *et al*. The C'JAAD: a French team for early intervention in psychosis in Paris. *Early Interv Psychiatry* 2018;12:243–9.

59 Akiskal HS, Hantouche EG, Bourgeois ML, *et al*. Toward a refined phenomenology of mania: combining clinician-assessment and self-report in the French EPIMAN study. *J Affect Disord* 2001;67:89–96.

60 Bonsack C, Gibellini Manetti S, Favrod J, *et al*. Motivational intervention to reduce cannabis use in young people with psychosis: a randomized controlled trial. *Psychother Psychosom* 2011;80:287–97.

61 Miles M, Huberman AM. *Analyse des données qualitatives*. 2e éd., [5e tirage]. Bruxelles,De Boeck, 2013: 1–626.

62 Le portail du Gouvernement suisse. *Ordonnance sur les essais cliniques dans Le cadre de la Recherche sur l'être humain (ClinO*, 2013.