Ensemble programme for early intervention in informal caregivers of psychiatric patients

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Study Protocol, Statistical Analysis Plan and Informed Consent Form

S. Rexhaj et D. Martinez, La Source, School of Nursing Sciences, HES-SO University of Applied Sciences Western Switzerland, Lausanne.

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s.rexhaj@ecolelasource.ch

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

Table of contents

STUDY PROTOCOL **2**
STATISTICAL ANALYSIS PLAN **8**
INFORMED CONSENT FORM **9**

Study protocol

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 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 standardized individualized 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 generalization 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 (1). This 22-item scale uses a five-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 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 (DSAS) 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 organized 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 authorization to be contacted.

Patient and Public Involvement

No patient involved

Interventions

Ensemble programme

Ensemble is a brief individualized 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 two days of specific training), addressed to the informal caregiver and delivered independent of the patient's treatment. Figure 1 below 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.

Support as usual (SAU)

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 standardize 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.

Outcomes

Quantitative data gathered through various standard instruments will inform the main and secondary outcomes. Table 1 summarizes the expected results.

Table 1: 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 to 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 to SAU
	Is quality of life	*36-item Medical*	ANCOVA of T1-	Experimental group

	improved?	*Outcome Study Short-Form Health Survey - Mental Component Score*	T0, T2-T0, T0 as dependent, treatment condition as fixed factor	statistically and clinically significantly improved compared to 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 significantly reduced compared to 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 to SAU

SAU = Support As Usual

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 (2), the analysis of the categorization devices used by the participants will provide us with comprehensive insight into the types of experiences during the programme, different capacities and unmet needs.

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 .05 with a power of β =.80. The effect size of the expected difference between the two groups was equal to Cohen's d= .470. Using an a priori computation for ANCOVA, the proposed trial required a total sample size of 144 participants for the two arms, 72 in each arm. In the pilot study, one 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 pre- and posttest values will be examined using analysis of covariance (ANCOVA).

Allocation

The Research Electronic Data Capture (REDCap) platform will be used to randomize the 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 randomization. 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.

Data collection, management and analysis

Primary outcome

The BSI aims to assess psychological symptoms and psychological distress. It includes 53 items organized into 9 primary and clinically relevant symptom dimensions: 1) somatization; 2) obsessive-compulsive; 3) interpersonal sensitivity; 4) depression; 5) anxiety; 6) hostility; 7) phobic anxiety; 8) paranoid ideation; and 9) psychoticism (3). This scale also has three global distress indices: the GSI, the Positive Symptom Distress Index (PSDI) and the Positive Symptom Total (PST).

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 (1). 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 Life Orientation Test – Revised (LOT-R) developed by Scheier, Carver and Bridges (4) 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 versus pessimism. The LOT-R has been translated and validated in French, with good psychometric proprieties (internal consistency α=0.76) (5). 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 zero (strongly disagree) to four (strongly agree); the four filler items are not included in the total score calculation. Higher scores suggest more optimism.

The 36-item Medical Outcome Study Short-Form Health Survey (SF-36) developed by Ware and Sherbourne (6) 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 (PCS) and 2) the Mental Component Score (MCS) – are obtained by grouping the eight dimensions, and these two synthetic variables allow different populations to be compared.

The different standard measures will be used in the three standard evaluations (T0=pretest; T1=posttest 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, Skodol and Lavet (7) 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.

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.

The Satisfaction Scale concerning the Ensemble programme was developed and used in the pilot study (8). This scale will be used only in the posttest evaluation of the intervention group to show the participants' satisfaction.

Qualitative arm

The aim of the qualitative part of this project is to conduct a qualitative open and exploratory study. Qualitative data will be collected through semi-directive 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. Semi-directive interviews will be conducted at the end of the study with twenty 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 program (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 ten participants will randomly be selected and be contacted for participating in the qualitative study.

Analysis

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.

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 randomization phase will only access these data. The data set will be controlled by investigators and transferred to 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. They will perform the following functions:

- Consent checks (100%);

- Verification of raw data (1st participant all data; for the other participants several randomly selected data);
- Verification of 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, depersonalization, and anonymization

Ethics and dissemination

The research protocol received full authorization 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 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 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 (9). 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 (9), the research project will be interrupted and the ethics committee will be notified about the circumstances within 15 days according to HRO Art. 212 (9). 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/

Statistical Analysis Plan

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 pre- and posttest values will be examined using an analysis of covariance (ANCOVA) for each outcome variable for the quantitative data. Differences between pretest and posttest 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 posttest and follow-up. For within subjects, Cohen's d will be calculated between the pre- and posttest and between the pretest and follow-up, correcting for dependence among means.

Informed Consent form

01.10.2020, English version based on the original French version used in the study

Study title

Ensemble program: a clinical trial to evaluate its effect

Ensemble program an early intervention for caregivers of psychiatric patients: a randomized controlled trial

This study is organised by : Rexhaj Shyhrete and Favrod Jérôme, La Source, School of Nursing sciences HES-SO, Lausanne

Dear Sir/Madam,

We would like to invite you to take part in our research project. This information sheet describes the research project.

Detailed information

Aims of the study

This study focuses on the difficulties in maintaining optimal psychological health and quality of life among family caregivers of patients with severe psychiatric disorders. Potential difficulties that may have a negative impact on the health of informal caregivers are generally linked to a high level of burden. This is why the Ensemble program, an early intervention to enable them to better preserve their health while fulfilling their role as caregiver, was developed. Preliminary results indicate a significant improvement in their psychological health. The five-session brief intervention enables caregivers to take a step back from their caregiving role. The first session enables the informal caregiver to take stock of his or her needs, difficulties, painful emotions and social resources, accompanied by a healthcare professional such as a nurse or psychologist. Over the following three sessions, the professional provides tailored support, based on the first assessment session. The final session provides an opportunity to take stock and plan next steps based on the family member's needs. The aim of this study is to determine whether the Ensemble program improves the psychological health, quality of life and optimism of informal carers, and reduces the burden related of the mental of the person they care for. The study will also assess the sustainability of Ensemble's potential benefits in a two-month follow-up after participation in the program. This study will allow us to test the clinical efficacy and potential sustainability of the Ensemble program. The results of this study will therefore provide essential information on how to offer adapted and effective support to family caregivers.

Selection of potential study participants

Participation is open to all people who are informal caregivers for people with psychiatric disorders. The following criteria must be met: 1) be a relative caregiver of a person with psychiatric disorders and have a burden score of at least 20 on the French Zarit Burden Interview (ZBI) scale, thus identifying at least a mild burden (Hébert, Bravo, & Girouard, 1993), 2) be at least 18 years old and 3) speak French.

General information about the study

This research project follows on from an initial pilot study carried out in the adult psychiatry department of the CHUV in collaboration with Ilot (an association for family members with mental health problems) and the La Source, School of Nursing Sciences Lausanne. The pilot study enabled us to build and validate the acceptability of the Ensemble program with 21 informal caregivers. As the preliminary results were promising, we decided to test the program's effectiveness with a larger number of informal caregivers living in French-speaking Switzerland. This project starts in September 2019 and will run for four years. We hope to be able to recruit 160 volunteer relatives.

To evaluate the effects of the Ensemble program, you will be randomly assigned to one of two groups: either the intervention group or the control group. If you're in the intervention group, you'll start the Ensemble program as soon as possible. On the other hand, if you are in the control group, you could benefit from the Ensemble program once the study is over. Project participants complete research questionnaires at three points in time (1) at the start of the project, 2) two months later and 3) the last at four/five months, to enable a comparison to be made between informal caregivers who follow the Ensemble program at the start of the project and those who have to wait. You meet one of the research assistants to help you fill in the various questionnaires. These assistants do not know whether you received the Ensemble program at the start of the project or afterwards. At the end of the project, a group of 20 participants will also be randomly selected to take part in individual interviews to qualitatively assess the effects of the Ensemble program.

Your involvement in this project will last approximately five months, including 4x1H to complete the informed consent and research questionnaires, and 5x1H to benefit from the Ensemble program. If you are in the intervention group, you will start the Ensemble program after completing the research questionnaires. The program then runs for a maximum of two months. The five meetings will be arranged between you and the professional, either once a week or once every two weeks. The program sessions take place at a location of your choice, either at home, at the Institut et Haute école de la santé, La Source in Lausanne, or at another consultation location such as Espace Proches, which will enable you to have individual meetings in a calm and confidential environment. If a meeting cannot take place (due to travel obligations, inability to get to the site, etc.), the intervention can exceptionally take place by videoconference. We do this because no two meetings can be more than 10 days apart.

If, on the other hand, you are assigned to the control group, you will fill in research questionnaires at three evaluation points: 1) at the start of the project, 2) at two months and 3) at the end. You will then benefit from the Ensemble program of five professional support sessions.

Research questionnaires enable us to assess your state of health (Brief Symptom Inventory - BSI), your quality of life (Quality of Life Questionnaire SF36), your optimism (Life Orientation Questionnaire LOT-R) and your burden (Zarit Scale), as well as the social functioning of the person you care for (Occupation and Social Functioning Questionnaire SOFAS).

At the end of the study, twenty participants will be selected to explore their experience of the Ensemble program through an individual interview. Two groups of participants will be included in this phase, those who have benefited greatly from the program (G1; n=10) and those who have benefited less (G2; n=10).

This selection will enable us to better understand the added value of the Ensemble program and identify areas for improvement. This interview will be recorded by an omnidirectional microphone (Marantz audio in MP3 format) and then transcribed verbatim into Microsoft Word. We need to record this interview to ensure the transcription of the interview. Once the transcription is complete, your recording will be destroyed. If you agree in principle, we will contact you for this qualitative evaluation at the end of the study. More detailed information will be provided at the appropriate time. You will have time to examine these conditions, and you will be free to disagree even if you sign the agreement in principle at the start of the project.
In addition, video recordings can also be made to help the professional accompanying you on the Ensemble program develop his or her skills. These video recordings will be accessible to the professional accompanying you and to his or her supervisor (Shyhrete Rexhaj or Jérôme Favrod). Some of these video recordings will also be the subject of a specific analysis designed to enrich pedagogy and develop the various professional skills of the Ensemble program.

If you participate in this process, you will be informed in greater detail about the educational objectives of these video recordings. If you agree in principle, the professional who will follow you during the Ensemble program will give you more detailed information. You will have time to examine these conditions, and you will be free to disagree even if you sign the agreement in principle at the start of the project.

All this research data and your personal contact details will be transmitted to the research team responsible for this project, which will keep them securely and may contact you at various stages of the project, subject to your agreement in principle.

We carry out this study in compliance with Swiss legislation. We also follow all internationally recognized guidelines. The study has been reviewed and approved by the relevant cantonal ethics commission. You will also find a description of the study on the website of the Swiss Federal Office of Public Health: www.kofam.ch (SNCTP000003434).

Procedure for participants
The table below shows the measurement times and the time taken to participate in the Ensemble program, depending on whether you are in the control or intervention group.

		Intervention group	Control group
Project start	Filling in standardized questionnaires with a research assistant (1H)	√	√
	Ensemble program (5x1H per week or max. every two weeks)	√	
Two months away from the start	Filling in standardized questionnaires with a research assistant (1H)	√	√
Four/five months into the project	Filling in standardized questionnaires with a research assistant (1H)	√	√
	Participation in a one-to-one meeting (maximum 1H30) (only 20 participants)	√	
End of the study			
	Ensemble program (5x1H per week or max. every two weeks)		√

Benefits for participants
By participating in this project, you benefit from the Ensemble program free of charge. If the positive results of the Ensemble program be confirmed, the support you will receive by participating in this project will help you to step back from your role as informal caregiver and find solutions to better cope with the psychiatric illness of your loved one. The results of the study could prove important in the future for other caregivers going through a similar experience to yours.

Participants' rights
Your participation is entirely voluntary. If you choose not to participate, or if you choose to participate and change your mind during the study, you will not have to justify your refusal. This will not affect your usual support. You can ask any questions you may have about the study at any time. Please contact one of the people listed at the end of this information sheet.

Participant obligations
As a study participant, you will be required to:

- complete the research questionnaires
- to attend the meetings scheduled as part of the Ensemble avec le professional program.

Risks and constraints for participants
Given that this is a complementary intervention to usual support, the risks are minimal. However, measuring individual needs, painful emotions and social networking may cause suffering in the face of the need to step back. Planned follow-up interviews will be tailored to your needs and should not present any additional risks. Also, the random assignment (intervention or control group) requires that participants in the control group be more patient than participants in the intervention group to benefit from the support offered by the Ensemble program.

Other treatment options
You are not obliged to take part in the study. If you decide not to take part, it will still be possible to be advised by the investigators about other support options for informal caregivers.

Discoveries during the study
You will be informed of any discoveries made during the study that are relevant to your health.

Data protection
We comply with all legal provisions on data protection. Your personal data and data relating to your well-being and quality of life are protected and used in encrypted form. Only a limited number of people can view your data in unencrypted form, and then only for the purposes of carrying out the tasks required for the project. Encryption means that all identifying data (e.g. name, date of birth, etc.) is replaced by a code (e.g. surname and first name will be replaced by initials with a combination of letters (“dummy initials”) that have no connection with the real initials (e.g. 'AAA', 'BBB'). The code remains permanently within the institution. People who do not know this code cannot link this data to your person. In the case of a publication, the aggregated data are therefore not attributable to you as a person. Your name will never appear on the Internet or in a publication. Occasionally, scientific journals require the transmission of individual data (raw data). If individual data must be transmitted, they are always coded and therefore do not allow you to be identified as an individual. All people involved in the study in any way whatsoever are

bound by professional secrecy. All data protection regulations are observed, and you have the right to inspect your data at any time.
During the study, inspections may be carried out. These inspections may be carried out by the ethics commission that authorized the study. Investigators may be required to disclose your personal data for the purposes of these inspections. All persons involved are bound by professional secrecy.

During the project, your data will be entered into a secure software package called REDCap, access to which is restricted to those involved in the study. At the end of the project, your coded data will be stored on a secure platform called FORS.

Withdrawal from the study
You may withdraw from the project at any time if you wish. The personal data relating to your well-being and quality of life collected up to that point will be coded and analysed in the same way as for the other participants and then rendered completely anonymous.

Compensation for participants
If you participate in this study, you will not receive any compensation.

Compensation for damages
La Source, School of Nursing Sciences' insurance as sponsor covers any damage incurred during the study.

Study funding
The study is financed by the Swiss National Science Foundation.

Contact person(s)
If you have any doubts, concerns or emergencies during or after the study, you can contact one of the following people at any time:

Rexhaj Shyhrete, professeur associée HES, La Source, School of Nursing Sciences, HES-SO University of Applied Sciences Western Switzerland, Avenue Vinet 30, 1004 Lausanne/ 079 103 18 16
Favrod Jérôme, La Source, School of Nursing Sciences, HES-SO University of Applied Sciences Western Switzerland, Avenue Vinet 30, 1004 Lausanne/ 079 447 31 57

Written consent for participation in a research project

Please read this form carefully. Don't hesitate to ask questions if you don't understand something or need clarification.

Study BASEC number : **(After submission to the relevant ethics committee) :**	2019-01181
Study title : (Scientific and common titles)	**Ensemble program an early intervention for caregivers of psychiatric patients: a randomized controlled trial** **Ensemble program: a clinical trial to evaluate its effect**
Responsible institution :	La Source, School of Nursing Sciences, HES-SO University of Applied Sciences Western Switzerland, Avenue Vinet 30, 1004 Lausanne
Study location :	French-speaking Switzerland
Investigators responsible for the project on site :	REXHAJ SHYHRETE FAVROD JÉRÔME
Participant : **(Print name and surname) :** **Date of birth :**	☐ Woman ☐ man

- I declare that I have been informed orally and in writing by the investigator in charge and/or his undersigned research collaborator of this study, of the objectives and progress of the study.
- I am taking part in this study voluntarily and accept the contents of the information sheet I have been given on the above-mentioned study. I have had sufficient time to make my decision.
- I have received satisfactory answers to the questions I asked in connection with my participation in the study. I have kept the information sheet and received a copy of my written declaration of consent.
- I have been informed of the availability of other support for caregivers.
- I accept that the competent specialists of the study sponsor and the relevant Ethics Commission may consult my raw data for the purpose of carrying out checks, provided that the confidentiality of this data is strictly maintained.
- I will be informed of any findings that have a direct impact on my health.
- I am aware that my personal data and those relating to my well-being and quality of life may be transmitted for research purposes within the framework of this project only and in coded form.
- I can revoke my consent to take part in the study at any time and without having to justify myself, without having any adverse repercussions on my situation as a family member or that of the person I am caring for. However, the data collected to date will be analyzed.
- I am informed that the civil responsibility of La Source, School of Nursing Sciences covers any damage I may suffer as a result of the project.

Place, date	Signature of participant

By placing an X in the following Yes box, I agree to take part in a qualitative interview at the end of this study.

Yes : ☐ **No :** ☐

By placing an X in the following Yes box, I agree to participate in video recordings useful for supervision.

Yes : ☐ **No :** ☐

By placing an X in the following Yes box, I agree to participate in video recordings useful for educational research.

Yes : ☐ **No :** ☐

Certification by investigator/scientific collaborator: I certify that I have explained the nature, importance and scope of the study to the participant. I declare that I have fulfilled all my obligations in connection with this project in accordance with applicable law. Should I become aware, at any time during the project, of any factors that might affect the participant's consent to take part in the project, I undertake to inform him/her immediately.

Place, date	Print name and surname of investigator/scientific collaborator providing information to participants. Signature of investigator/scientific collaborator

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