Santé mentale et psychiatrie
Laboratoire d'Enseignement et de Recherche

Title of the study

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

This study is conducted by: Rexhaj Shyhrete and Favrod Jérôme, La Source, School of Nursing Sciences, HES-SO University of Applied Sciences Western Switzerland, Lausanne

Dear Sir/Madam,

We invite you to participate to our research project. This information sheet describes the research project.

Detailed information

1. Objectives of the study

This study concerns the difficulties to maintain an optimal psychologic health state and a good quality of life for the informal caregivers providing support to persons with severe psychiatric disorders. The possible difficulties that can impact negatively the health of informal caregivers are generally linked to a high level of burden. An early intervention, Ensemble program, allowing to promote their health state, was therefore developed. The primary outcomes indicate a significative improvement of their psychological state of health. This brief intervention includes five sessions conducted by a healthcare practitioner as nurses or psychologists and allows the informal caregiver to take a step back on his/her supporting role. The first session helps the informal caregiver to observe his/her needs, difficulties, painful emotions and social network resources.
The professional provides during the next three sessions adjusted and tailored support according to the first assessment session. The last session allows to review what has been done and to plan the next steps according the informal caregiver needs. This study must allow us to know if the Ensemble program improves informal caregivers' psychological health state, quality of life, optimism and reduce their burden induced by the psychiatric disorder of the person they are supporting. The study will also allow to assess the durability of the potential advantages of Ensemble with a two months follow-up set. This study will allow us to assess the clinic efficacity and potential feasibility of the Ensemble program. This study outcomes will provide essential information on the way of providing adjusted and efficient support to informal caregivers.

2. Selection of people being able to participate in the study

The study is open to every informal caregiver who provides close support to persons with psychiatric disorders. The following criteria must be met: 1) being an informal caregiver providing support to a person with psychiatric disorder and having a burden score of at least 20 on the French Zarit Burden Interview (ZBI) which indicates a lower burden (Hébert, Bravo and Girouard, 1993), 2) being at least 18 years old and 3) speaking French.

3. General Information about the study

This research project follows a first pilot study conducted in an adult psychiatric service from the CHUV in collaboration with l'Ilot (association of informal caregivers of psychiatric disorders) and with La Source, School of Nursing Sciences, HES-SO University of Applied Sciences Western Switzerland. The pilot study helped to construct and to validate the acceptability of the Ensemble program with 21 informal caregivers. The preliminary outcomes were promising, therefore we decided to test the efficacity of the program with a larger number of informal caregivers living in the Switzerland French speaking area. This project runs for 4 years starting from September 2019. We hope being able to recruit 160 informal caregivers' volunteers.
To test the effects of the Ensemble program, you will be randomly assigned into two groups: either intervention group or control group. In the intervention group you will begin rapidly the Ensemble program. However, if you are assigned into the control group, you will be able to benefit from the Ensemble program once the study is finished. Study participants fill in research questionnaires three times: (1) at the beginning of the project, (2) two months later and (3) four/five months later, in order to compare the informal caregivers following the Ensemble program at the beginning of the project and the informal caregivers who need to wait. You will meet

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a research assistant to help you fill in the different questionnaires. This assistant does not know if you have received the Ensemble program at the beginning of the project or if you will receive it after. At the end of the project, a group of 20 participants will also be randomly selected in order to participate to individual interviews to evaluate qualitatively the effects of the Ensemble program.

Your involvement in the project lasts approximately five months: four times one hour to fill in approved consent form and research questionnaires and five times one hour to receive the Ensemble program. If you are in the intervention group, you will begin the Ensemble program after filling in the research questionnaires. The program can take up to two months. The five sessions will be planned between you and the professional once a week or one every two weeks. The program sessions can be held at any place of your choosing, at your place, at one of our facilities in La Source, School of Nursing Sciences in Lausanne or at another consultation location in l'Espace Proches facility for example. This will allow a calm and confidential space for the individual. If a session cannot happen (moving obligation, impossibility to come, etc.), the intervention could exceptionally be given by visio-conference. We need to proceed that way because the time between two meetings cannot be more than ten days.
However, if you are in the control group, you will fill in the research questionnaires three times 1) at the beginning of the project, 2) two months later and 3) at the end. Then, you will be able to benefit from the Ensemble program of five support sessions with a professional.

The research questionnaires allow us to assess your current psychological health state (the BSI Global Index Score), your quality of life (the 36-item Medical Outcome Study Short-Form Health Survey), your optimism (Life Orientation Test-Revised (French version)) and your burden (Zarit Burden Interview (French version)). The social and occupational functioning of the person that you are providing support to (the Social and Occupational Functioning Assessment Scale (SOFAS)) will also be assessed.

At the end of the study, 20 participants will be selected and interviewed in an individual interview to explore their experience of the Ensemble program. 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 less benefited (G2; n=10). This selection will allow us to better understand the added value of the Ensemble program and to identify areas for improvement. The interviews will be recorded with an omnidirectional microphone (Marantz audio MP3 format) and will be transcribed on Microsoft Word. We need the recordings to ensure the interviews' transcription. Your recording will be destroyed after transcription. If you approve, we will contact you for this qualitative evaluation at the end of the study. Further information will be given in due course. You will have time to examine the conditions and will be free to refuse even if you have had already approved at the beginning of the project. Furthermore, video recordings can also be realized to help the professional who is meeting you in the Ensemble program, develop his/her skills. These recordings will be accessible by the professional him/herself and his/her supervisor (Shyhrete Rexhaj or Jérôme Favrod). Some of these recordings will also be used as specific analyses to enrich pedagogy and develop the different professional skills of the Ensemble program.

If you agree to participate to this process, you will be given detailed information about the pedagogic aims of theses video recordings. If you approve, the professional who will follow you during the Ensemble program, will give you further information. You will have time to examine these conditions and will be free to refuse even if you already have signed the approved consent at the beginning of the project.

All these research data and your personal data will be given to the manager research team of this project who will safely keep them. The team will contact you, following your approved consent, during the different steps of the project.
We conduct this study in respect of the swiss legislation prescriptions. We follow all the international recognized guidelines. The cantonal ethics Committee have controlled and authorized the study. You will find a study description on the Federal Office of Public Health website: https://www.kofam.ch/fr/portail-snctp/recherche/74009/etude/47320; NCT04020497 | SNCTP000003434.

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4. Conduct for the participants

The table below allows you to visualize the moments of measures and the duration of the Ensemble program participation either you are in the control or intervention group.

		Intervention group	Control group
Beginning of the project	Filling in the standard questionnaires with a research assistant (1H)	√	√
	Ensemble program (5x1h per week or up to every two weeks)	√	
Two months later	Filling in the standard questionnaires with a research assistant (1H)	√	√
Four/five months later:	Filling in the standard questionnaires with a research assistant (1H)	√	√
	Participation to an individual interview only 20 participants (up to 1H30)	√	
End of the study			
	Ensemble program (5x1h per week or up to every two weeks)		√

5. Benefits for the participants

This project allows you to benefit freely from the Ensemble program. In case of positives Ensemble program outcomes are confirmed, the support that you will get during the project will help you to step back from your informal caregiver role and find solutions to better cope with your relative psychiatric disorder. The study outcomes could prove significant later, to the informal caregivers that live a similar experience as your own.

6. Participants rights

Your participation is entirely free. If you choose not to participate or if you come back from your decision during the study, you will not have to justify your decision. This will change nothing to your usual support. You can ask all the questions linked to the study at any time. You may contact one of the persons indicated at the end of this information sheet, to do so.

7. Participants obligations

As a study participant, you will have to:

- Fill in the research questionnaires
- Participate to the planned Ensemble program meetings with a professional

8. Risks and constraints for the participants

As the intervention is a complement to usual support, risks are low. However, assessing your individual needs, painful emotions and social network as you take a step back, can generate pain. The planned meetings will be adjusted following your needs and should not provoke supplementary risks.
Also, the randomly repartition (intervention or control group) requires that participants of control group be more patient than the participants of intervention group to benefit from the support offered in Ensemble program set.

9. Others treatment possibilities

You are under no obligation to participate to the study. If you decide not to take part in it, it will be possible to be advised on the other possibilities of informal caregiver support.

10. Discoveries during the study

Any appearing discovery during the study relevant to your health will be transmitted.

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11. Data confidentiality

We respect all legal dispositions relating to the data protection. Your personal and your data relating to your well-being and your quality of life are protected and used coded. Only a limited number of people can consult your data under a non-coded way and will exclusively use it to fulfill their duties within the scope of the study. Coding means that all data allowing to identify you (for example name, date of birth, etc.) are replaced with a code (ex: name and first name will be replaced by initials with a combination of letters as factices initials) that have no link to your true initials (for example 'AAA', 'BBB'). The code stays permanently in our institution. People who do not know the code cannot linked these data to you. In a publication, data will be anonymised. Your name will not appear of the internet or any publication. Sometimes, scientific journals ask for individual data (raw data). In this case, individual data will be coded and will not allow to identify you as a person. All involved persons in this study are bounded by professional secrecy. All guidelines relating to data protection are respected. You have the right to consult your data at any time.

During its course, the study can be inspected. The ethical commission who has controlled and authorised this study can conduct inspections. Investigators might communicate your personal data for the needs of these inspections. All people are bounded by professional secrecy.

During the project, your data will be inserted into a secured software named REDCap. Only staff members of this project will have access to these data. At the end of the project, your data will be coded and will be stored in a secured platform named FORS.

12. Withdraw from the study

You can withdraw at any time. The personal and relevant data of your wellbeing and quality of life will be coded and analyzed as the other participants and then fully anonymized.

13. Participants compensation

If you participate to this study, you will not receive any compensation.

14. Compensation of incurred damages

In the event of study-related damage or injuries, the liability of the institution Institut et Haute Ecole de la Santé, La Source provides compensation.

15. Funding of the study

This study is financed by the Swiss National Science Foundation.

16. Contact persons

In case of any doubts, concerns or emergencies during or after the study, you can contact at any time one of the following persons:

Rexhaj Shyhrete, HES Associate professor, La Source, School of Nursing Sciences, HES-SO University of Applied Sciences Western Switzerland, Av. Vinet 30 1004 Lausanne/079 103 18 16

Favrod Jérôme, HES Full Professor La Source, School of Nursing Sciences, HES-SO University of Applied Sciences Western Switzerland, Av. Vinet 30 1004 Lausanne/ 079 447 31 57

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Written consent declaration for the participation of a research project

Read with caution this form. Do not hesitate to ask any questions if you do not understand anything or if you need precisions.

Study BASEC number: (After submission to the competent ethics commission)*:*	
Study title*:* (Scientific title and usual title)	**Ensemble Programme an early intervention for informal caregivers of psychiatric patients: a randomized controlled trial** **Programme Ensemble: clinical trial to test its effect**
Leader institution:	La Source, School of Nursing Sciences, Avenue Vinet 30, 1004 Lausanne
Localization of the study:	French-speaking Switzerland
Monitoring managers and investigators of the project on the site:	Rexhaj Shyhrete Favrod Jérôme
Participant: (PRINT NAME and FIRST NAME): Date of birth:	☐ woman ☐ man

- I declare having been informed, by the responsible investigator and/or his/her research coworker undersigned, orally and in writing, of the objectives and conduct of the study.
- I take part in this study voluntarily and I accept the content of this above-mentioned study information sheet that I was given. I have had enough time to take my decision.
- I received satisfactory answers to the questions that I have asked about my participation to the study. I keep this information sheet and receive a copy of my written consent declaration.
- I have been informed of the other possible support for informal caregivers.
- I accept that the competent specialist of the sponsor of the study and Ethics Commission can consult my draw data to proceed to controls, in the case where the confidentiality of these data are strictly assured.
- I will be informed of any discoveries with a direct impact on my health.
- I know that my personal data and the data relating to my well-being and my quality of life can be transmitted for research purposes in this project set only and under a coded form.
- I can whenever and without justification withdraw my consent to participate in this study, without any negative repercussion on my informal caregiver situation and the situation of the person I take care of. Data collected until my withdraw will be analyzed.
- I am informed that the liability of the institution Institut et Haute Ecole de la Santé, La Source provides compensation in case of any damages that could incur in this project.

Location, date	Participant signature

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Putting an X in the Yes box, I agree to participate to a qualitative interview for research purposes.

Yes: ☐ **No :** ☐

Putting an X in the Yes box, I agree to participate to the video recordings useful for the supervisions.

Yes : ☐ **No :** ☐

Putting an X in the Yes box, I agree to participate to the video recordings useful for the pedagogy research

Yes : ☐ **No :** ☐

Investigator/research coworker confirmation : Hereby, I confirm having explained to the participant the nature, the importance and the scope of the study. I declare satisfying all legal obligations relating to this project. If I should notice, whenever during the project realization, susceptible elements of influencing on the consent of the participant to take part in the project, I engage to inform him/her immediately.

Location, date	PRINT NAME and FIRST NAME of the investigator/research coworker assuring the information to the participants. Investigator/research coworker signature