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Study Title	Resources-Oriented Salutogenic (ROS) Intervention for Improving Sense of Coherence in Pre-Diabetes Population: A Pilot Randomized Controlled Trial
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INFORMATION SHEET

Resources-Oriented Salutogenic (ROS) Intervention for Improving Sense of Coherence in Pre-Diabetes Population: A Pilot Randomized Controlled Trial

Phase 1 (Qualitative study): Individual interviews

You are invited to participate in the above project conducted by Yaqian Liu, who is post-graduate student at the School of Nursing in The Hong Kong Polytechnic University and currently under the supervision of Dr Angela Y.M Leung. The project has been approved by the PolyU Institutional Review Board (PolyU IRB) (or its Delegate) (Reference Number: HSEARS20231206006).

The aims of this project are to explore pre-diabetes population's experience towards receiving diabetes risk information in China, and what preferred available resources they will employ to cope with prediabetes situation by adopting the lens of SoC and Salutogenic perspective. The findings will be as foundation for salutogenic intervention development among prediabetes population.

This study will include adults above 18 years, who have diagnosed with pre-diabetes made by medical staffs, or undergone HbA1c testing (5.7-6.4%). Individuals who have already diagnosed with diabetes will be excluded.

You are invited to attend online individual interviews which will take you about 40-60 minutes via Zoom meeting. A set of guiding questions will be raised by the moderator. You are invited to respond to the questions based on your experiences and personal views.

The interview should not result in any undue discomfort, but you will need to audio-recorded.

The information you provide as part of the project is the research data. Any research data from which you can be identified is known as personal data. Personal data does not include data where the identity has been removed (anonymous data). We will minimize our use of personal data in the study as much as possible. The researcher and his team, supervisor will have access to personal data and research data for the purposes of the study. Participants have the right to request access to and correction of personal data provided for the project in writing at any time during the study period. Responsible members of The Hong Kong Polytechnic University may be given access for monitoring and/or audit of the research.

All information related to you will remain confidential and all study data will be stored with a password and will not be stored on personal devices. The information collected will be kept until seven years after project completion. The Hong Kong Polytechnic University takes reasonable precautions to prevent the loss, misappropriation, unauthorized access or destruction of the information you provide.

You have every right to withdraw from the study before or during the measurement without penalty of any kind.

If you have any questions, you may ask our helpers now or later, even after the study has started.

You may contact Miss Yaqian Liu (tel. no.: +852 9060 4953/ email: yaqian.liu@connect.polyu.hk) or Dr. Angela Y.M. Leung (tel. no.: +852 2766 5587 / email: angela.ym.leung@polyu.edu.hk) of PolyU under the following situations:

a. if you have any other questions in relation to the study;
b. if, under very rare conditions, you become injured as a result of your participation in the study; or
c. if you want to get access to/or change your personal data before (the expiry date).

In the event you have any complaints about the conduct of this research study, you may contact Secretary, PolyU Institutional Review Board in writing (institutional.review.board@polyu.edu.hk) stating clearly the responsible person and department of this study as well as the Reference Number.

In case of a serious adverse event[1], please report to the Principal Investigator/Chief Investigator immediately and the Principal Investigator/Chief Investigator will be required to report it to the PolyU IRB within 48 hours upon the receipt of your report.

Thank you for your interest in participating in this study.

Prof. Angela Y.M. Leung
Principal Investigator/Chief Investigator

[1] SAE is any adverse event that:

- Results in death
- Is life threatening, or places the participant at immediate risk of death from the event as it occurred
- Requires or prolongs hospitalization
- Causes persistent or significant disability or incapacity
- Results in congenital anomalies or birth defects
- Is another condition which investigators judge to represent significant hazards

(Reference: NIA Adverse Event and Serious Adverse Event Guidelines. https://www.nia.nih.gov/sites/default/files/2018-09/nia-ae-and-sae-guidelines-2018.pdf)

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Resources-Oriented Salutogenic (ROS) Intervention for Improving Sense of Coherence in Pre-Diabetes Population: A Pilot Randomized Controlled Trial

Phase 2 (feasibility study): Survey + focus group interviews

You are invited to participate in the above project conducted by Yaqian Liu, who is post-graduate student at the School of Nursing in The Hong Kong Polytechnic University and currently under the supervision of Dr Angela Y.M Leung. The project has been approved by the PolyU Institutional Review Board (PolyU IRB) (or its Delegate) (Reference Number: HSEARS20231206006).

The aims of this project are to assess feasibility and acceptability of ROS intervention on pre-diabetes population in China.

This online ROS intervention program will guide prediabetes population in Hong Kong to explore and identify available resources surrounding them, and encourages them use their preferred resources and skills to cope with the challenges during prediabetes and promote health behaviors leading to a Salutogenic orientation. This project includes 8 online group sessions (90 minutes weekly). The online intervention group lectures via Zoom meeting mainly provide important health resource information and examples of resource use, including diabetes prevention, nutritional guidance, physical exercise, stress management, social support, and peer support, etc. In addition, a closed Facebook group will be created to deliver resources booklet, zoom meeting links, as well as encourage participants share your daily salutogenic recording, give comments and thumps-up by group members. You are also invited to fill in a set of questionnaires two times at the commencement and after 8 weeks, as well as a focus group interview lasting about 60 minutes. A set of guiding questions will be raised to you by the moderator. You are invited to respond to the questions based on your experiences and personal views.

This study will include subjects with pre-diabetes and low or moderate level of sense of coherence. Participants will be excluded if they: have a history of diabetes, using hypoglycemic drugs, pregnancy, lactation, disability, or other physical limitations; presence of serious health complications might affect the HbA1c level such as anemia, renal failure, liver disease; participation in a similar intervention program within 3 months.

The questionnaires and interviews should not result in any undue discomfort, but you will need to audio-recorded.

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Resources-Oriented Salutogenic (ROS) Intervention for Improving Sense of Coherence in Pre-Diabetes Population: A Pilot Randomized Controlled Trial

Phase 3 (Pilot RCT): Survey

You are invited to participate in the above project conducted by Yaqian Liu, who is post-graduate student at the School of Nursing in The Hong Kong Polytechnic University and currently under the supervision of Dr Angela Y.M Leung. The project has been approved by the PolyU Institutional Review Board (PolyU IRB) (or its Delegate) (Reference Number: HSEARS20231206006).

The aims of this project are to assess the preliminary effectiveness of ROS intervention in improving sense of coherence and other health outcome measures in pre-diabetic population.

This online ROS intervention program will guide prediabetes population to explore and identify available resources surrounding them and encourages them use their preferred resources and skills to cope with the challenges during prediabetes and promote health behaviors leading to a Salutogenic orientation. Participants will be randomized assigned to one of two groups on Facebook. The intervention group will receive 8 online group sessions (90 minutes weekly) delivered via Zoom meeting. These sessions mainly provide important health resource information and examples of resource use, including diabetes prevention, nutritional guidance, physical exercise, stress management, social support, and peer support, etc. In addition, a closed Facebook group will be set up that participants can share their daily salutogenic recordings with other participants, give comments and thumps-up to these recordings in the Facebook. While participants in control group will usual care (that is, general health education about lifestyle) in the Facebook and undergo monthly educational follow-ups via Facebook message to check the practical application of healthy lifestyle. All participants are also invited to fill in a set of questionnaires three times (at baseline, after 2-month, after 5-month), two times telephone follow-ups (at 3-month and 4-month), as well as two times fingertip blood collection for HbA1c test (at baseline and 5-month), The overall assessments duration will last 5 months.

This study will include subjects with pre-diabetes and low or moderate level of sense of coherence. Participants will be excluded if they: have a history of diabetes, using hypoglycemic drugs, pregnancy, lactation, disability, or other physical limitations; presence of serious health complications might affect the HbA1c level such as anemia, renal failure, liver disease; participation in a similar intervention program within 3 months.

The questionnaires and interviews should not result in any undue discomfort, but you will need to audio-recorded. Two HbA1c tests (before the start of the study and 5 months later) will be conducted at the Gerontological Nursing Laboratory (Block A 107) of the Hong Kong Polytechnic University. A registered nurse will use a small sterile lancet to puncture finger and collect 2μl capillary fingertip blood, which may cause tiny pain, or someone will do not feel pain. You will be informed beforehand about the procedure for mental readiness and advised to apply pressure to their fingertips for 5 minutes to both ease any pain and halt bleeding. Psychological support will also be available to lessen any anxiety or unease during the process. To minimize infection risks, the registered nurse will employ aseptic techniques. Furthermore, participants will be given the contact information of the Principal Investigator (PI) to report any adverse events that may occur.

The information you provide as part of the project is the research data. Any research data from which you can be identified is known as personal data. Personal data does not include data where the identity has been removed (anonymous data). We will minimize our use of personal data in the study as much as possible. The researcher and his team, supervisor will have access to personal data and research data for the purposes of the study.

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CONSENT TO PARTICIPATE IN RESEARCH

Resources-Oriented Salutogenic (ROS) Intervention for Improving Sense of Coherence in Pre-Diabetes Population: A Pilot Randomized Controlled Trial

Phase 1 (Qualitative study): Individual interviews

I _____ hereby consent to participate in the captioned research conducted by Yaqian Liu under the supervision of Prof. Angela YM Leung, School of Nursing, The Hong Kong Polytechnic University, Hong Kong.

I understand that information obtained from this research may be used in future research and published. However, my right to privacy will be retained, i.e. my personal details will not be revealed.

The procedure as set out in the attached information sheet has been fully explained. I understand the benefit and risks involved. My participation in the project is voluntary.

I acknowledge that I have the right to question any part of the procedure and can withdraw at any time without penalty of any kind.

Name of participant _____

Signature of participant _____

Name of Parent or Guardian (if applicable) _____

Signature of Parent or Guardian (if applicable) _____

Name of researcher _____

Signature of researcher _____

Date _____

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CONSENT TO PARTICIPATE IN RESEARCH

Resources-Oriented Salutogenic (ROS) Intervention for Improving Sense of Coherence in Pre-Diabetes Population: A Pilot Randomized Controlled Trial

Phase 2 (feasibility study): focus group interview

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CONSENT TO PARTICIPATE IN RESEARCH

Resources-Oriented Salutogenic (ROS) Intervention for Improving Sense of Coherence in Pre-Diabetes Population: A Pilot Randomized Controlled Trial

Phase 3 (Pilot RCT): Survey + qualitative interview

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Date _____

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