Full study protocol and statistical analysis plan

Official Title of the study:

Implementation of a Community-based Resilience Promotion Program to Only-child Loss Parents in China

Date of the document:

28th October 2017

Contents:

1. Participant Flow

Recruitment Details

We will choose a community in Changsha, where principle investigators' institution located, to recruit the participants. This community has a number of around 260 only-child loss(OCL) parents, and has a social organization to serve the bereaved parents. The recruitment will start at Nov 1st 2017 and last around one week. The recruitment announcement will be distributed to the participants via social worker in their daily online chat group or through telephone call.

Pre-assignment Details [*]

We firstly will assess the recruited people to ensure meeting the inclusion and exclusion criteria. The inclusion criteria are made according to the official documents. OCL Family is one that has given birth to only one child but now has no living birth or adopted child, and the bereaved mother is older than 49 years (medically maximum age for fertility in China).

Those with serious mental disorders or physical illnesses who were not able to complete the intervention and evaluation questionnaire will be excluded.

Than the final enrolled participants can be sure and randomized assignment will be conducted.

Enrollment (total, anticipatory)	**150**			Record the number of the eligible and the excluded
Allocation (randomized)	**Group A**	**Group B**	**Group C**	Record the number of the received and the unreceived
	50	**50**	**50**	
Follow-up (immediately after intervention)				The numbers of each follow-up stages are uncertain by now. But in the latter research, we will record information of the lost and the continued.
Follow-up (3-month after intervention)				
Follow-up (12-month after intervention)				

Arm/Group Information *

There are three groups in the study.

Arm/Group Title *

Positive psychology therapy group= Group A

Resilience promotion therapy group= Group B

Controlled routine activity group= Group C

Arm/Group Description *§

Positive psychology therapy group will be intervened by a psychotherapy developed from an American psychologist. The positive psychology therapy lasts 8 weeks, and has a group intervention in each week. The themes of each week are start-up, time gift, positive mind, three good things, a thankful heart, life train, active service, end-up.

Resilience promotion therapy group will be intervened by another psychotherapy developed by the researchers. The resilience promotion therapy lasts 8 weeks, and also has a group intervention in each week. The themes of each week are start-up, mutual help, trust in yourself, thanksgiving feedback, care for yourself, emotional management, end-up.

Controlled routine activity group will have routine service delivered by social workers. This group will have routine service delivered by social workers.

Period(s) *

There is only one stage in the study.

Period Title *

Overall Study.

Started *

There will be 150 participants initiating the intervention.

Those 150 participants will be randomly assigned to three groups with around 50 participants in each group.

Completed *

We will do follow-up, and the number in each follow-up will be recorded.

Milestone Title [*]

Before the intervention, we will measure the participants, , and the stage is defined as T0.

We will do follow-up immediately after intervention, 3-month after intervention, 12-month after intervention, defined as T1, T2, T3 respectively.

Reason Not Completed Type [*]

We will record the exact reason (Adverse Event) why participants do not complete the study. The reason may be death, lack of efficacy, lost to follow-up, illness, withdrawal by subject or others.

2. Baseline Characteristics

Arm/Group Information *

Chi-square test will be applied to figure out the difference of enumeration data among three groups. ANOVA will be applied to test the difference of measurement data among three groups. F values and χ^2 values will be displayed to show the baseline data are no different in three groups.

Arm/Group Title *

Positive psychology therapy group

Resilience promotion therapy group

Controlled routine activity group

Arm/Group Description *§

All the recruited participants will be numbered and randomly allocated into three groups by random number table. The grouping results will be announced to the participants according to the random number table.

Overall Number of Baseline Participants *

There will be 150 participants initiating the intervention.

Baseline Measure Information *

A group of demographic characteristics will be measured in the study, including gender, age, marital status, income per month, gender of lost kid, length of lost kid.

Baseline Measure Title *

- Age * : Continuous(years)
- Gender * : Female, Male
- Marital status: with a spouse, without a spouse
- Income per month: Categorical:
    - <=1000 RMB
    - >1000 and <2000 RMB
    - >=2000 RMB
- Gender of lost kid: Female, Male
- Length of lost kid: Continuous(years)

Measure Type *

- Count of Participants: Gender, Marital status
- Mean: Age, Length of lost kid
- Number: Gender of lost kid, Income per month

Measure of Dispersion *

- Standard Deviation
- Inter-Quartile Range
- Full Range

Baseline Measure Data *

The value(s) for each baseline measure, for each group and overall cannot obtain right now since the study has not been started.

3. Outcome Measures

Outcome Measure Information *

A questionnaire will be used during each measurement, including several scales in it.
The saliva test of Dehydroepiandrosterone will also be done in each measurement.

Outcome Measure Type *

- Primary

Outcome Measure Title *

- Psychological resilience: a kind of ability to bounce back from adversity measured by Connor-Davidson Resilience Scale (CD-RISC). It is a self-reported scale by adding up 25 items and the total score ranges from 0-100, with higher score reflects higher resilience. The differences within two times frame are the changes of psychological resilience
- Depression: depressive mood in recent two weeks measured by Zung Self-rated Depression Scale (SDS). It is a self-reported scale by adding up 20 items and the total score ranges from 20-80, with higher score reflects higher depression. The differences within time frames are changes of depression
- Subjective well-being: a feeling of happiness measured by Campbell Index of well-being (IWB). It is a self-reported scale by adding up 8 items and the total score ranges from 2.1-14.7, with higher score reflects higher subjective well-being. The differences within time frames are change of subjective well-being
- Social avoidance: the phenomenon that a person is absent from normal social interaction with others measured by Social Avoidance and Distress Scale(SAD). It is a self-reported scale by adding up 14 items and the total score ranges from 0-14, with higher score reflects social avoidance. The differences within time frames are the changes of social avoidance
- Sleeping quality: a reflection of one's mood in recent month measured by Pittsburgh sleep quality index(PSQI). It is a self-reported scale, with total score higher than 19 reflects sleeping disorder. The differences within each time frames are the changes of sleeping quality
- Post traumatic growth: the positive growth after an adversity measured by Post Traumatic Growth Inventory(PTGI). It is a self-reported scale by adding up 24 items and the total score ranges from 0-120, with higher score reflects more growth. The differences within time frames are changes of post-traumatic growth
- Health care behavior: a person's self-care behavior measured by Health Promoting Lifestyle Profile-Ⅱ(HPLP-Ⅱ). It is a self-reported scale by adding up 40 items in four dimensions. The total score ranges from 40-160, with higher score reflects better health care behavior. The differences within time frames are changes of health care behavior
- Concentration of dehydroepiandrosterone in saliva: a kind of hormone that reflects the person's psychological stress collected by Sarstedt saliva collection tube by chewing the sterile cotton strips for 60 seconds. It will be tested by enzyme-linked immunosorbent assay (ELISA) with Kit Number of HT81012 and Origin site in Canada PLlabs

Outcome Measure unit *

The psychological resilience, depression, subjective well-being, social avoidance, sleeping quality, post traumatic growth, and health care behavior are measured by scales with no unit.
Dehydroepiandrosterone has its concentration unit of pg/ml.

Outcome Measure Time Frame *

There will be four measurements, before the intervention, immediately after intervention, 3-month after intervention, and 12-month after intervention. They are defined as T0, T1, T2, T3 respectively.

Analysis Population Information

Overall Number of Participants Analyzed *

There will be 150 participants totally enrolled in the study.

Outcome Measure Data Table

Measure Type *

- Mean

Measure of Dispersion/Precision *

- Standard Deviation

Outcome Data *

The measurement value(s) for each outcome measure cannot obtain right now since the study has not been started.

Statistical Analysis Overview

Comparison Group Selection [*]

We will compare three groups' data.

Type of Statistical Test [*]

- Superiority
- Other (descriptive analysis)

P-Value [*]

P-Value will be set at 0.05.

Method [*]

- ANOVA
- Chi-Squared
- t-Test, 2-Sided
- Other: repeated measurement of variance analysis within different measurements among different groups

Estimation Parameter [*]

- Mean Difference (Final Values)

4. Adverse Event Information

Time Frame *§

The intervention lasts 8 weeks, and we will record the adverse event each week.

Than we will do follow-up immediately after intervention, 3-month after intervention, and 12-month after intervention. we will record the adverse event at each follow-up.

Adverse Event Reporting Description [*]

We will add relevant information about adverse event after finishing the study.

Collection Approach for Table Default *§

- Systematic Assessment: The psychotherapist will routinely determine whether or not certain adverse events have occurred through regular investigator assessment during intervention and in each follow-up.
- Non-Systematic Assessment: Self-reporting by participants or occasional assessment by the psychotherapist.

Adverse Event Term *

The most possible adverse event may be the psychological discomfort because the participants are experiencing bereavement.

We will provide information for in three tables summarizing adverse events in each group, including all-cause mortality, serious adverse events, and other (not including serious) adverse events.

Organ System *

- Psychiatric Disorders

5. Limitations and Caveats

There may be several limitations.

We may not reach the target number of participants because the bereaved parents present social avoidance and may not interested in the intervention. We will invite social worker to help recruiting and make calls to all registered bereaved parents.

The measurements are mostly based on self-reported scales and may lead to unreliable data. We will give instruction before fulfilling the questionnaire to ensure the participants understood.

6. Certain Agreements

Are all PIs Employees of Sponsor? *

- No: The principal investigator is not an employee of the sponsor

There is no agreement between the agent(university) and the principal investigators. The principal investigators are graduate students in the university. The principal investigators (PIs) can discuss the results of the study at a scientific meeting or any other public or private forum, or to publish in a scientific or academic journal information concerning the results of the study.

7. Results Point of Contact

Name or Official Title *

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