

Full study protocol and statistical analysis plan

Official Title of the study:

A Community-based Resilience Group Psychotherapy for Only-child Loss Parents in China

Date of the document:

6th June 2022

Contents:

1. Participant Flow
2. Baseline Characteristics
3. Outcome Measures
4. Adverse Event Information
5. Limitations and Caveats
6. Certain Agreements
7. Results Point of Contact

1. Participant Flow

Recruitment Details

We will choose two communities in Changsha, where principle investigators' institution located, to recruit the participants. This community has a social organization to serve the bereaved only child lost parents. The recruitment started at Nov 1st 2017. The recruitment announcement was distributed to the participants via social worker in their daily online chat group or through telephone call.

Pre-assignment Details [*]

We firstly assessed 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.

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

Enrollment (total, anticipatory)	80		Record the number of the eligible and the excluded
Allocation (randomized)	Intervention group	Treat as usual group	Record the number of the received and the unreceived
	40	40	
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 two groups in the study.

Arm/Group Title *

Resilience therapy group= **Intervention group**

Controlled routine activity group= **Treat as usual group**

Arm/Group Description *§

Resilience therapy group was intervened by a 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 80 participants initiating the intervention with around 40 participants in each group.

Completed *

We did follow-up, and the number in each follow-up was recorded.

Milestone Title [*]

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

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

Reason Not Completed Type [*]

We recorded 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, withdrawing by subject or others.

2. Baseline Characteristics

Arm/Group Information *

Chi-square test was applied to figure out the difference of enumeration data among three groups. ANOVA was applied to test the difference of measurement data among three groups. F values and χ^2 values was displayed to show the different in two groups.

Arm/Group Title *

Resilience therapy group

Controlled routine activity group

Arm/Group Description *§

All the recruited participants was numbered and randomly allocated into two groups by random number table. The grouping results was announced to the participants.

Overall Number of Baseline Participants *

There was 80 participants initiating the intervention.

Baseline Measure Information *

A group of demographic characteristics was 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 was listed below.

Table 1 Socio-demographic variables among two groups

	Resilience therapy group (n=42)	Controlled group (n=38)	χ^2 /t	P
Gender				
Male	16	13	0.13	0.78
Female	26	25		
Religion*				
Yes	41	35	1.27	0.25
No	1	3		
Marital status				
Married/remarried	35	28	1.11	0.29

Divorced/widowed	7	10		
Education level				
Junior high school and below	19	21	0.80	0.37
Senior high school and above	23	17		
Per capita monthly income (¥)*				
≤1000	4	5	2.04	0.36
1001-2000	17	20		
≥2000	21	13		
Chronic disease				
Yes	14	15	0.32	0.56
No	28	23		
Gender of child				
Male	34	27	1.08	0.29
Female	8	11		
Reason of child loss*				
Acute disease	13	11	1.09	0.77
Chronic disease	15	14		
Accident	12	9		
Suicide or others	2	4		
Grandchild				
Yes	33	28	0.26	0.60
No	9	10		
Age of participants (year)	62.35±6.14	60.13±5.57	1.71	0.09
Age of child (year)	27.68±7.71	28.90±5.11	0.74	0.45
Length of child loss (year)	12.04±5.91	10.67±4.32	1.17	0.24

Note: Income is valued in Chinese currency unit, with ¥2,000 RMB≈\$314 USD. *The number of grids with theoretical number less than 5 exceeds 1/5, Fisher exact probability was applied.

3. Outcome Measures

Outcome Measure Information *

A questionnaire was used during each measurement, including several scales in it. The saliva test of Dehydroepiandrosterone was also 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
- 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, and post traumatic growth are measured by scales with no unit.

Dehydroepiandrosterone has its concentration unit of pg/ml.

Outcome Measure Time Frame *

There were 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 was 80 participants totally enrolled in the study.

Outcome Measure Data Table

Measure Type *

- Mean

Measure of Dispersion/Precision *

- Standard Deviation

Outcome Data *

Table 2 Descriptive data, change and effect size between group comparisons for primary and secondary outcomes at four time points

		M(SD) of control group	M(SD) of intervention group
Resilience	T0	51.84 (15.58)	55.19 (12.04)
	T1	52.61 (13.97)	65.86 (13.87)
	T2	53.79 (15.11)	65.05(10.28)
	T3	63.12(13.91)	64.53(14.16)
Depression	T0	54.42(7.90)	51.63(6.43)
	T1	52.95(7.98)	44.75(10.15)
	T2	50.76(7.22)	44.36(8.32)
	T3	50.70(7.28)	40.21(10.92)
PTG	T0	56.13(15.68)	53.50(14.67)
	T1	58.66(15.47)	70.62(14.66)
	T2	61.05(16.06)	71.19(11.62)
	T3	61.16(14.99)	71.57(11.32)
IWB	T0	8.65(2.34)	8.98(1.94)
	T1	8.81(1.99)	10.41(2.44)
	T2	9.25(1.90)	10.43(1.83)
	T3	9.42(2.20)	10.53(1.99)
SAD	T0	10.89(1.75)	10.12(2.35)
	T1	10.07(1.31)	4.95(4.85)
	T2	9.15(2.06)	4.32(4.49)
	T3	6.99(3.83)	4.50(4.57)
Sleep	T0	7.25(3.71)	7.76(3.32)

DHEA	T1	7.14(3.48)	7.31(2.85)
	T2	6.63(3.22)	7.90 (5.83)
	T3	7.68(4.02)	6.43(3.00)
	T0	43.95(27.21)	48.86(20.47)
	T1	45.40(32.23)	50.38(31.44)
	T2	43.19(29.33)	50.87(27.01)
	T3	44.25(22.59)	50.87 (32.67)

Statistical Analysis Overview

Comparison Group Selection [*]

We compared two 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 lasted 8 weeks, and we recorded the adverse event each week.

We did follow-up immediately after intervention, 3-month after intervention, and 12-month after intervention, and recorded the adverse event at each follow-up.

Adverse Event Reporting Description [*]

We added relevant information about adverse event after finishing the study.

Collection Approach for Table Default *§

- Systematic Assessment: The psychotherapist routinely determined whether or not certain adverse events had 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 *

Most possible adverse event may be the psychological discomfort because the participants are experiencing bereavement. We provided 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. The measurements are mostly based on self-reported scales and may lead to unreliable data. We gave 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 *

Professor: Jingping Zhang

Position title: Director of Nursing Psychology Research Center

Organization Name *

Nursing Psychology Research Center, Xiangya School of Nursing, Central South University

Phone: *§ +86-13873127168

Email: *§ jpzhang1965@csu.edu.cn