Full study protocol and statistical analysis plan

Official Title of the study:

An online 5-week professional identity group psychotherapy for nursing student during clinical rotation practice

Date of the document:

3rd June 2020

Contents:

1. Participant Flow

Recruitment Details

We will choose School of Nursing, FudanUniversity to recruit the participants. The recruitment will start at May 1st 2020. The recruitment announcement will be distributed to the participants via online notice transmission software used by the school.

Pre-assignment Details [*]

We firstly will assess the recruited people to ensure meeting the inclusion and exclusion criteria. Than the final enrolled participants can be sure and randomized assignment will be conducted.

Enrollment (total, anticipatory)	**110**		Record the number of the eligible and the excluded
Allocation (randomized)	**Group A**	**Group B**	Record the number of the received and the unreceived
	55	**55**	
Follow-up (immediately after intervention)			Record the number of the received and the unreceived

Arm/Group Information *

There are two groups in the study.

Arm/Group Title *

Intervention group= Group A

Controlled group= Group B

Arm/Group Description *§

Intervention group: Students will be intervened by an online 5-week professional identity group psychotherapy.

Controlled group will receive online messages of self-care knowledge forward by researchers.

Period(s) *

There is only one stage in the study.

Period Title *

Overall Study.

Started *

There will be 110 participants initiating the intervention.

Those 110 participants come from two classes in the same grade. One will be randomly allocated as the intervention group, the other will be control group.

Completed *

We will do follow-up post intervention, and the number in the 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, defined as T1.

Reason Not Completed Type [*]

We will record the exact reason (Adverse Event) why participants do not complete the study. The reason may be not interested, lack of efficacy, lost to follow-up, 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 between two groups. ANOVA will be applied to test the difference of measurement data between two groups. F values and χ^2 values will be displayed to show the baseline data are no different in two groups.

Arm/Group Title *

Intervention group= Group A

Controlled group= Group B

Arm/Group Description *§

Those 110 participants come from two classes in the same grade. One will be randomly allocated as the intervention group, the other will be control group.

Overall Number of Baseline Participants *

There will be 110 participants initiating the intervention.

Baseline Measure Information *

A group of demographic characteristics will be measured in the study, including gender, age, income per month of the family, etc.

Baseline Measure Title *

- Age * : Continuous(years)
- Gender * : Female, Male
- Income per month: Categorical:
    - <=1000 RMB
    - >1000 and <2000 RMB
    - >=2000 RMB
- The reason of being a nurse: nominal:
    - Out of interest
    - Advice from parents
    - Others

Measure Type *

- Count of Participants: Gender
- Mean: Age
- Number: Income per month, The reason of being a nurse

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.

Outcome Measure Type *

- Primary and secondary

Outcome Measure Title *

- Professional identity: professional identity in recent one week measured by Chinese Profession identity scale for nursing student. It is a self-reported scale by adding up 17 items and the total score ranges from 17-85, with higher score reflects higher professional identity.
- Career self-efficacy: career self-efficacy in recent one week measured by Chinese career self-efficacy scale for nursing student. It is a self-reported scale by adding up 27 items and the total score ranges from 27-135, with higher score reflects higher career self-efficacy.
- Stress: a reflection of one's perceived stress in recent month measured by the subscale from the Depression, Anxiety, and Stress Scale (DASS-21). It is a self-reported scale, with 7 items in the stress subscale scoring from 0-21. The higher score, the higher stress.
- Resilience: resilience in recent one week measured by Chinese version of Connor-Davidson Resilience Scale-10. It is a self-reported scale by adding up 10 items and the total score ranges from 0-40, with higher score reflects higher resilience.
- General rating: several descriptive question to gather the feedback of the intervention.

Outcome Measure unit *

The professional identity, career self-efficacy, stress, and resilience are measured by scales with no unit.

Outcome Measure Time Frame *
There will be two measurements, before the intervention and immediately after intervention. They are defined as T0, T1.
Analysis Population Information
Overall Number of Participants Analyzed *
There will be 110 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 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 lasts around 35 days, with 5 times, and we will record the adverse event at each time.
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.
We will provide information for in two tables summarizing adverse events in each group, including serious adverse events, and other (not including serious) adverse events.
Organ System *
- Psychiatric Disorders

5. Limitations and Caveats

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

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