

STUDY PROTOCOL of “Fun · Feel · Share” Lyrics-writing and Singing Show – A Pilot Project

1. General Information

- Protocol title: **"Fun · Feel · Share" Lyrics-writing and Singing Show – A pilot project**
- Name of the sponsor: Health Care and Promotion Fund
- Name of Principal Investigator: Dr Ho Sai Yin Daniel
- Title of the principal investigator: Associate Professor, School of Public Health, Li Ka Shing Faculty of Medicine, The University of Hong Kong;
- Name of the co-investigators: Prof Lam Tai Hing, Dr Wang Man Ping Kelvin, and Dr Sun Yuying

2. Background

This project adopts the five elements of Seligman's well-being theory (Seligman, 2002 & 2011). PERMA includes five pillars of well-being that can help people reach a life of fulfillment, happiness and meaning: Positive emotions (P), Engagement (E), Positive relationships (R), Meaning (M) and Accomplishment (A). "Joyful@HK" was launched as a territory-wide intervention and mental health promotion campaign in Hong Kong. Three main elements are being advocated: sharing, mind, and enjoyment (SME). The elements being promoted in Joyful@HK reflect the principles of positive psychology and the positive interventions supported by evidence of efficacy (Sheldon and Lyubomirsky, 2006; Sin and Lyubomirsky, 2009; Gander et al., 2012).

Similar project – "3Hs Family Drama Project 「家添戲 FUN」計劃" was organized from March 12 to October 2013. Cluster randomized controlled trial design with two intervention arms included watching the drama live at school, or being given a DVD recording to watch with family members at home with weekly worksheets and a control arm was incorporated. The results suggested that fun, feel and share elements were well received by the participants and effectiveness was observed in improving their health behaviors and parent-child interactions.

The "Fun · Feel · Share" Lyrics-writing and Singing Show will organize by The Boys' & Girls' Clubs Association of Hong Kong and funded by the Health & Care Promotion Fund of the Food and Health Bureau. The Project will organize a Lyrics-writing and Singing Competition in secondary schools with student and family entries with a lyrics-writing workshop and a short talk on SME focusing on praising family members and knowledge of adolescent mental health problem (in particular the anxiety disorders) and mental well-being.

Students are encouraged to submit SME worksheet, such as "Express Your Love to Family Member" after the workshops. Students will use family praising as theme for lyrics-writing and submit records of SME during lyrics-writing and singing; and they will have the entries

submitted in the form of DVD / YouTube. A Lyrics-writing and Singing Show and Award Ceremony will be held after the competition. Lastly, a wisdom sharing session will be held to school social workers and teachers to promote best practice at the end. The main targets are 720-900 secondary students from 3-4 secondary for the lyrics-writing workshop; and 300 students and their family members for the SME Lyrics-writing and Singing Show. 25-40 entries will be received from secondary school students and their family members. The School of Public Health, University of Hong Kong, will evaluate the effectiveness of the Project.

3. Objectives

- **Process evaluation:** To assess the satisfaction level and the coverage of students and their family members towards the “Fun · Feel · Share” Lyrics-writing and Singing Competition and Show.
- **Outcome evaluation:** To promote the concept of Sharing, Mind and Enjoyment (SME); to increase the knowledge and understanding about mental health for adolescents and adults.

4. Selection and Withdrawal of subjects

4.1 Subject inclusion criteria

Secondary students in participating secondary schools

4.2 Subject exclusion criteria

Students who cannot read Chinese

5. Research design

5.1 School selection

3-4 schools in the project will be selected and invited to join in the evaluation study. Cluster randomized controlled trial design will be adopted.

5.2 Intervention arms

The evaluation will include 2 arms (each having 1-2 schools and 360-450 students):

- **2 Intervention schools:** the lyrics-writing and singing workshop and a small talk was conducted first at the beginning of the programme, followed by the lyrics-writing competition held after the workshop. A lyrics writing and singing show and an award ceremony will be held at the end.
- **1-2 Waitlist schools:** Waitlist control receiving no intervention during evaluation period. The lyrics-writing competition will be held at the beginning of the programme. A lyrics writing and singing show, the award ceremony, and the lyrics-writing and singing workshop and a small talk will be held after the evaluation. Preferably, these schools should have similar characteristics with the intervention. They will be provided with the intervention after the evaluation period.

5.3 Assessments

- T1: before the lyrics-writing workshop (baseline)
- T2: immediately after the workshop (post intervention)
- T3: after the lyrics-writing competition (2-month after baseline)
- T4: after the singing show and award ceremony (4-month after baseline)

The above timing is for the intervention schools. Control school will complete the T1, T3 and T4 assessments about the same time as the matched intervention school.

5.4 Process Evaluation (Table 1)

a) T2 (Immediately after participating in the SME workshop)

The satisfaction, ratings and opinions on the SME workshop of students in the intervention group will be assessed quantitatively (questionnaire surveys).

Quantitative evaluation among students at T2 is embedded into outcome evaluation (refer to outcome evaluation below)

▪ Students

- Quantitative: questionnaire survey after participating the SME workshop
 - All students in the intervention school: n=360-450

b) T3 (2-month after baseline)

The satisfaction, ratings and opinions on the lyrics-writing competition of students in the intervention group will be assessed quantitatively (questionnaire surveys) and qualitatively (semi-quantitative evaluation e.g. content analysis). Quantitative evaluation among students at T3 is embedded into outcome evaluation (refer to outcome evaluation below)

▪ Students

- Quantitative: questionnaire survey after participating the lyrics-writing competition
 - All students in the intervention school: n=360-450
- Qualitative:
 - Semi-quantitative evaluation e.g. content analysis
 - All students who participated the lyrics-writing competition

c) T4 (4-month after baseline)

The satisfaction, ratings and opinions on the singing show of students and family members in the intervention group will be assessed quantitatively (questionnaire surveys) and qualitatively (focus group discussion). Quantitative evaluation among students at T4 is embedded into outcome evaluation (refer to outcome evaluation below). The satisfaction, ratings and opinions on "Fun · Feel · Share" Lyrics-writing and Singing Show programme of school principal/teacher/community partner in the intervention group will be assessed qualitatively (individual in-depth interviews)

- **Students**
 - Quantitative: questionnaire survey after participating the singing show
 - All students in the intervention school: n=360-450
 - Qualitative: brief (about 40 minutes) small group discussions
 - At least 2 groups, 8-12 students per school
 - These students are not required to complete the questionnaire survey above if the interviews are conducted at the same time
 - The interviews will be audio-recorded
 - Each interview is conducted by 1 interviewer and 1 assistant
- **Family members:**
 - Quantitative: brief questionnaire survey after participating the singing show
 - All family members who participated the singing show are invited, n=360-450
 - 1 assessment by questionnaire will be conducted with an expected response of 50%
 - Qualitative: (embedded in the above T4 parent survey)
 - At least 2 groups, 8-12 parents per group
 - These parents are not required to complete the questionnaire survey above if the interviews are conducted at the same time
 - The interviews will be audio-recorded
 - Each interview is conducted by 1 interviewer and 1 assistant
- **School principal/teacher/community partner:**
 - Qualitative: individual in-depth interview (about 60 minutes)

Table 1. Outline of process evaluation

Target	Timeline	Process evaluation (intervention group)	
		Quantitative	Qualitative
Students	T2	- 2 schools - n=360-450	
	T3	- 2 schools - n=360-450	- Semi-quantitative evaluation
	T4	- 2 schools - n=360-450	- 2 focus groups, n=16-24 - 8-12 students per school
Family members	T4	- 2 schools - n=360-450	- 2 focus groups, n=16-24 - 8-12 parents per group
School principals/teachers/ community partners	T4		- Individual in-depth interview - n=3

5.5 Outcome evaluation (Table 2)

Background, SME, parent-child interactions and subjective changes of students in intervention group and control group will be assessed quantitatively (questionnaire survey)

a) T1 (baseline) evaluation:

- Questionnaire survey in school halls (or classrooms if preferred)
 - All students in the participating schools: n=720-900
- Items: background, mental health knowledge, happiness, well-being, SME, parent-child interactions, hope

b) T2 (immediately after the lyrics-writing workshop) evaluation

- Questionnaire survey in school halls (or classrooms if preferred)
 - All students in 2 intervention schools: n=360-450
- Items: background, mental health knowledge

c) T3 (2-month after baseline) evaluation

- questionnaire survey in school halls (or classrooms if preferred)
 - All students in participating schools: n=720-900
- Items: background, mental health knowledge, happiness, well-being, SME, parent-child interactions, hope, subjective changes

d) T4 (4-month after baseline) evaluation

- questionnaire survey in school halls (or classrooms if preferred)
 - All students in participating schools: n=720-900
- Items: background, mental health knowledge, happiness, well-being, SME, parent-child interactions, hope, subjective changes

Table 2. Outline of outcome evaluation

Target	Outcome evaluation	
	Intervention Group	Control Group
Students	- T1, T2, T3, T4 surveys - 2 schools, n=360-450 - T2, T3 and T4 surveys includes process evaluation	- T1, T3, T4 surveys - 1-2 schools, n=360-450

6. Statistics

Descriptive findings will be presented as means and proportions with 95% confidence interval. Standard statistical methods for RCT (e.g. intention to treat) and subgroup analysis will be set a priori in the protocol which will be registered in clinicaltrial.gov. Missing data will be handled using ITT, LOCF or multiple imputation depending on the patterns of missing data. Clustering effect if any will be handled with statistical models (e.g. multi-level analysis) and regression models will be used to estimate the effect sizes of interventions.

7. Ethics

For the student questionnaires, an invitation letter detailing the questionnaires will be given to the students, explaining the arrangements of the voluntary questionnaires. Participants may discontinue participation at any time without penalty or loss.

8. Data handling and data keeping

All data collected during the course of research will be kept strictly confidential. Data will be handled and stored in locked cabinet and password-protected computers during and after completion of the study. The principal investigator (Dr Ho Sai Yin Daniel) and his appointed staff will be responsible for safekeeping the data. Only the research team and appointed staff will have access to the data during/after the study. The personal data will be kept for 3 years from the end of the study.

9. Compliance with the ICH_GCP

The protocol has complied with the ICH-GCP.

10. References

- Gander, F., Proyer, R.T., Ruch, W. et al., 2012. Strength-based positive interventions: Further evidence for their potential in enhancing well-being and alleviating depression. *Journal of Happiness Studies*, 14(4), pp.1241-1259.
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- Sheldon, K.M. and Lyubomirsky, S., 2006. How to increase and sustain positive emotion: The effects of expressing gratitude and visualizing best possible selves. *The Journal of Positive Psychology* 1(2), pp.73-82.
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