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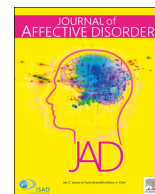
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Research paper

Feasibility of a group-based laughter yoga intervention as an adjunctive treatment for residual symptoms of depression, anxiety and stress in people with depression



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A B S T R A C T

Background: Laughter Yoga (LY) is a group-based intervention involving simulated laughter, gentle stretching, rhythmic breathing and meditation. There is some limited evidence that LY reduces depressive symptoms over the short term. However, the quality of previous LY studies is poor and none involved working-aged people with a clinical diagnosis of depression. Therefore, this study aimed to investigate the feasibility and potential efficacy of LY for improving residual mood, anxiety and stress symptoms in adults diagnosed with depression.

Methods: Fifty participants were randomised to the group LY intervention ($n = 23$) consisting of eight sessions over four weeks, or treatment-as-usual ($n = 27$). Participants completed the Depression Anxiety Stress Scale and the Short Form 12 item Health Survey at baseline (T0), post-intervention (T1) and at 3 months follow-up (T2). LY participants also completed a Client Satisfaction Questionnaire (CSQ8) at T1 and eleven participated in individual qualitative interviews at T2.

Results: The LY group had statistically greater decreases in depression and improvements in mental health related quality of life compared to the control group from T0 to T1. The CSQ8 scores indicated a favourable level of satisfaction with the LY intervention. The qualitative interviews highlighted aspects of the intervention that were effective and those requiring modification.

Limitations: Limitations include the small sample size and treatment-as-usual control group.

Conclusions: A full scale RCT of LY could be feasible if some modifications were made to the protocol/intervention. The intervention may be effective to improve depression and mental health related quality of life immediately post intervention.

1. Introduction

Depression is a relatively common mental health disorder affecting around 350 million people worldwide (Marcus et al., 2012; Kessler and Bromet 2013). The illness is associated with an impaired ability to function on a day-to-day basis (WHO 2016) and hence contributes significantly to the global burden of disease (Reddy 2010). Depression is treated using a range of pharmacological and psychosocial approaches, with outcome being highly influenced by social, environmental, biological and psychological factors (NICE 2009). Although pharmacological treatments are helpful for many people, some studies show that only one in three patients with Major Depressive Disorder reach remission with first-line antidepressant drugs (Rush et al., 2006). Residual symptoms such as depression and anxiety are also common, with numerous studies showing that over 50% of patients in remission report two or more residual symptoms (Miller et al., 1998; Nierenberg

et al., 1999; Nil et al., 2016).

Due to the limited effectiveness of pharmacological treatments for some people, alternative treatments for depression are increasingly popular. Consequently, these interventions have attracted the attention of researchers seeking to establish their effectiveness as treatment adjuncts. These treatments are generally well tolerated and include exercise, light therapy, mindfulness-based meditation, omega-3 fatty acids and yoga (Ravindran et al., 2009). A meta-analysis of traditional yoga for depression (Cramer et al., 2013) reported that severity of depressive symptoms reduced significantly over the short term when compared with standard care (a medium-large effect size of $SMD = -0.69$). Significant positive improvements in depressive symptoms were also observed when comparing yoga to relaxation and exercise interventions (effect sizes of 0.62 and 0.59 respectively). Exercise and yoga have also been shown to have moderately positive effects on anxiety (Saeed et al., 2010). The therapeutic mechanisms of yoga are

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thought to relate to positive influences on emotional regulation and a moderation of reactions to stressful events (Streeter et al., 2012). Studies suggest that yoga may improve mental well-being as it increases levels of dopamine, stimulates thalamic GABA release, reduces levels of plasma cortisol and increases serotonergic activity (Kjaer et al., 2002; Streeter et al., 2012).

Following the encouraging results of the effects of meditational and aerobic types of yoga on well-being (Pilkington et al., 2005) some limited research has been conducted to establish the efficacy of laughter yoga (LY) on psychological and physical well-being. LY was created by Dr Madan Kataria in India in 1995, it is a type of group based laughter exercise involving simulated laughter, gentle movement/stretching, rhythmic breathing and meditation (Bennett et al., 2015; Dolgoff-Kaspar et al., 2012). It has become increasingly popular worldwide and is now promoted as a low cost, low risk, less time-consuming intervention to improve well-being. Dr Kataria suggests that simulated laughter (not reliant on humour) has the same beneficial effects on the human body as genuine laughter, for example by reducing levels of stress related hormones (Kataria, 2005). Although there is a lack of substantial objective evidence for this claim, a recent study (Fujisawa et al., 2018) provides some indication that simulated laughter may have a positive impact on reducing cortisol levels in a similar fashion to that seen resulting from genuine laughter (Berk et al., 1989; Hubert et al., 1993). Fujisawa et al. (2018) controlled study randomised 120 healthy university students to a 30-minute single session of either LY, watching a comedy film or reading a non-humorous book. The results showed that participants who underwent LY had significantly reduced levels of salivary cortisol from baseline to 30 min after the intervention ($F = 4.33$, $p = 0.016$), whereas there was no improvement in the book reading group. However, the group of students who watched a comedy movie had higher reductions in cortisol than the LY participants ($F = 30.11$, $p < 0.001$) and the effects lasted longer. It is also hypothesised that the therapeutic effects of LY may result through actions on the same body systems as both yoga and genuine laughter; for example, by increasing serotonergic activity, promoting relaxation and through relieving muscle tension (Bennett and Lengacher, 2008; Shahidi et al., 2011; Bennett et al., 2015). In addition, LY may improve mood by triggering genuine and contagious laughter in a group setting, and through strengthening social bonds by laughing with groupmates (Pan and Yeh, 2016).

Robust clinical studies of LY are scarce, and most focus on the well-being of people without a diagnosis of mental illness, or with diagnoses of specific physical illnesses. A recent systematic review of group LY interventions for improving mental health in adults (Bressington et al., 2018) identified six experimental studies conducted with a range of different populations. Only one study has been published which tests the effects of LY in people with diagnosed mental disorders (Shahidi et al., 2011); which compared the effectiveness of LY, group exercise and usual treatment to improve depression and life satisfaction in a group of elderly moderately depressed females. The systematic review (Bressington et al., 2018) concluded that LY has a promising effect on depressive symptoms, with significant medium-large effect sizes in two studies over the short term. However, the reviewed studies were small and generally of poor methodological quality.

Due to popularity of LY and the lack of good quality evidence, there was a need to conduct rigorous studies testing the potential effects of the intervention and the feasibility of conducting a full scale RCT to improve the symptoms of adults diagnosed with depression. Therefore, this study aimed to investigate the feasibility, acceptability, satisfaction and potential efficacy of a group-based LY intervention for improving residual symptoms of mood, anxiety and stress in working-aged people with a diagnosis of depressive disorder.

2. Study objectives

- To determine the feasibility of conducting a full scale randomized

controlled trial.

- To examine acceptability and satisfaction of the LY intervention from patients' perspectives.
- To evaluate the potential effects of the group-based LY intervention compared with treatment as usual, on residual symptoms of depression, anxiety and stress.
- To evaluate the potential effects of the group-based LY intervention compared with treatment as usual, on health-related quality of life.

3. Methods

3.1. Study design

This feasibility study used a non-blinded parallel-group randomised controlled trial design. We prospectively registered the study protocol on 18/05/2017 with ClinicalTrials.gov (reference: NCT03163940).

3.2. Study setting

The study was carried out from August 2017 to March 2018 in the Community Psychiatric Service of a large psychiatric hospital in Hong Kong. The service provides comprehensive multidisciplinary community psychiatric case management and treatment for a population of approximately 1.2 million people in the geographical catchment area.

3.3. Participants

All study participants were community-dwelling people who had a diagnosis of depressive disorder and at the point of recruitment were being treated in the community by the Community Psychiatric Service.

Participant inclusion criteria were: (a) male or female aged from 18–60 years; (b) diagnosed with and being treated for a depressive disorder (F32, F33: ICD-10-CM) as confirmed by a psychiatrist; (c) not receiving any other yoga, psychosocial or humour based intervention (currently or within the last three months); (d) able to commit to attend the LY groups; (e) current use of antidepressant and with no plans to change the medication during the next 3 months; (f) able to speak Chinese or English; (g) able to provide written informed consent and considered safe and competent to participate in the study (as suggested by their psychiatrist); (f) with baseline residual symptoms of depression (DASS score ≥ 10), in addition to anxiety (DASS ≥ 8) and/or stress (DASS ≥ 15).

Exclusion criteria were: (a) a history of bipolar disorder or schizophrenia; (b) physical health problems which may present risks if engaging in LY (i.e. hernia, injuries, etc. determined by their psychiatrist); (c) having co-morbidity of another chronic physical and/or mental health problem such as learning disability, substance misuse disorders and organic brain diseases; (d) receiving any talking therapies at recruitment or throughout the study period.

3.4. Recruitment, randomisation and blinding

The nurse consultant of the participating community mental health team was asked to nominate patients who met the study inclusion criteria. Each eligible participant was given a unique identification number in sequence according to their alphabetical order of surname. A list of random identification numbers was generated by an online external randomisation service (researchrandomizer.com) and this list was used to determine the order in which patients were approached by their keyworker. Participants were recruited in three consecutive cohorts over a three-month period.

After written informed consent was obtained, the baseline measurements were completed by participants supervised by a trained research assistant (RA). Only participants found to meet the DASS score inclusion criteria progressed to the randomisation stage, where they were individually assigned to either the LY or TAU control group (also

using random numbers generated by the randomisation service). All randomisation was carried out by a researcher not otherwise directly involved in the study. Due to the nature of the intervention it was not practical to blind participants or study personnel to treatment allocation after baseline assessments were conducted.

3.5. Ethical considerations

Ethical approval was obtained from the University's Research Ethics Committee and the Cluster Clinical Research Ethics Committee of the Hong Kong Hospital Authority prior to commencement of the study. The keyworker discussed the study with potential participants in detail, provided additional written information, and ascertained their capacity to provide informed consent. Potential participants were given adequate time to consider their decision. All participants were made aware that once they had provided written informed consent they could withdraw from the study at any point without needing to give a reason and without any negative treatment-related consequences. Potential risks to participants (i.e. emotional distress) arising from taking part in the study were monitored (and where necessary managed) by the LY group facilitator and a member of nursing staff at the group sessions.

3.6. Sample size

Our sample size estimation was based on previous literature that recommends feasibility studies adopt sample sizes of between 24 and 50 (Sim and Lewis, 2012; Julious, 2005) and a review of feasibility studies registered on the United Kingdom Clinical Research Network, which reported that the median sample size for studies with continuous outcome measures was 30 (Billingham et al., 2013). Therefore, assuming a minimum of 30 participants is required in each group, and taking into account a 20% drop-out rate observed in many psychosocial intervention studies (Van Daele et al., 2012), our target sample size was 36 in each study group (i.e., 72 participants in total).

3.7. Interventions

3.7.1. LY intervention

The LY groups were offered twice weekly, for 45 min each time. Each participant was asked to attend a total of 8 groups (over 4 weeks). Each group was designed to have a maximum of 12 participants. The LY groups were facilitated by one experienced certified lead LY trainer and supported by one of the three co-investigators who were also certified LY facilitators. In order to maintain consistency in the content of the LY group intervention across different groups the lead facilitator followed a pre-designed intervention content schedule. The three co-investigators monitored the lead LY trainer's fidelity to this planned schedule of activities using a pre-designed checklist.

Each session included the four essential steps of LY with integrated laughter meditation and grounding exercises. The intervention also provides an opportunity to connect with other people in the group in an enjoyable way. The four steps of LY are composed of (1) warm up exercises (e.g. clapping and body movement), (2) deep breathing exercises, (3) childlike playfulness and (4) laughter exercises (e.g. greeting laughter, lion laughter and other self-created laughter exercises, and closing cheers).

Laughter meditation involves focusing on the experience of laughter and the associated bodily sensations. The resulting focus on the present-moment is hypothesized to provide temporary relief from negative thoughts and rumination whilst providing an opportunity for a release of negative emotions. Unconditional or genuine laughter is often experienced during laughter meditation; this can become infectious and trigger laughter in other people within the group, hence creating greater connections with group members. The grounding exercises generally consist of a brief guided relaxation with deep breathing and are designed to enable participants to ground the energy of laughter

and relax after each laughter exercise. The childlike playfulness aspect of LY is integrated into many of the laughter exercises through acting and improvisation, it is intended to reduce inhibitions, cultivate a sense of openness and convert simulated laughter into genuine laughter during the groups. This sense of playfulness and openness is reinforced at the end of each laughter exercise by swinging the arms and chanting "Very good", "Very good" and "Yay". An example of a laughter exercise incorporating playfulness is the "milkshake laughter" exercise, in which participants pour and mix the ingredients of two imaginary glasses of milk by chanting "Aeee" and then laugh when pretending that they are drinking the milkshake. A selection of different LY exercises were conducted in each group to avoid repetition. Participants were also given a LY workbook and encouraged to practice the LY exercises individually outside the group sessions (i.e. at home).

3.7.2. Treatment-as-usual

Both the intervention and TAU control groups received their usual routine community mental health care (including medications) and attended medical outpatient appointments as determined by their individual needs. We asked TAU participants to refrain from joining any LY group or other humour-based formal intervention during the study time. The RA also asked the participants if they had attended such sessions during the follow-up assessments.

3.7.3. Data collection

The RA and keyworkers collected the baseline data at recruitment (including sociodemographic data, quantitative measures and relevant clinical data). The RA collected all follow-up outcome data and conducted the qualitative interviews. The primary and secondary outcomes were recorded at baseline, after the 4 weeks' intervention period (within one week of finishing the groups), and at 3 months after finishing the intervention.

All participants completed a demographic questionnaire specifically developed for this study. Information gathered included their age, sex, marital status, living situation, education level, employment status, comorbid physical illnesses, duration of depression diagnosis and prescribed medications for mental health.

3.7.4. Establishing the feasibility of conducting a full scale RCT

In order to assess the feasibility of conducting a full scale RCT, pertinent data was recorded throughout the study, including: participation/refusal rate, drop-outs, intervention attendance rates, adverse events and reasons for non-participation/withdrawal. LY participants were also asked to keep a diary (contained within the LY workbooks) of when and for how long that they may have practiced the intervention outside the facilitated groups and during the follow-up period in order to ascertain the feasibility of home practice.

3.8. Establishing acceptability and satisfaction of the LY intervention from patients' perspectives

Individual qualitative interviews were conducted to explore patients' views on the acceptability of group LY. Twelve patients who received the LY intervention were invited to a short interview (maximum of 25 min) with the RA at three months' follow-up. To obtain a broad spectrum of views about the intervention, participants were purposively selected for interview based on their level of participation and outcomes (i.e. two participants from each of the following groups: full attendance, partial attendance (60–90%), infrequent attendance (< 50%), and three participants each from: DASS improved, DASS no change/deterioration).

In order to ascertain patients' satisfaction with the intervention all LY participants were asked to complete the Chinese language version of the Client Satisfaction Questionnaire (CSQ8) (Attkisson and Zwick, 1982; Attkisson, 2012) in the week post intervention. The CSQ8 is a widely used and well-established standardised self-report measure of

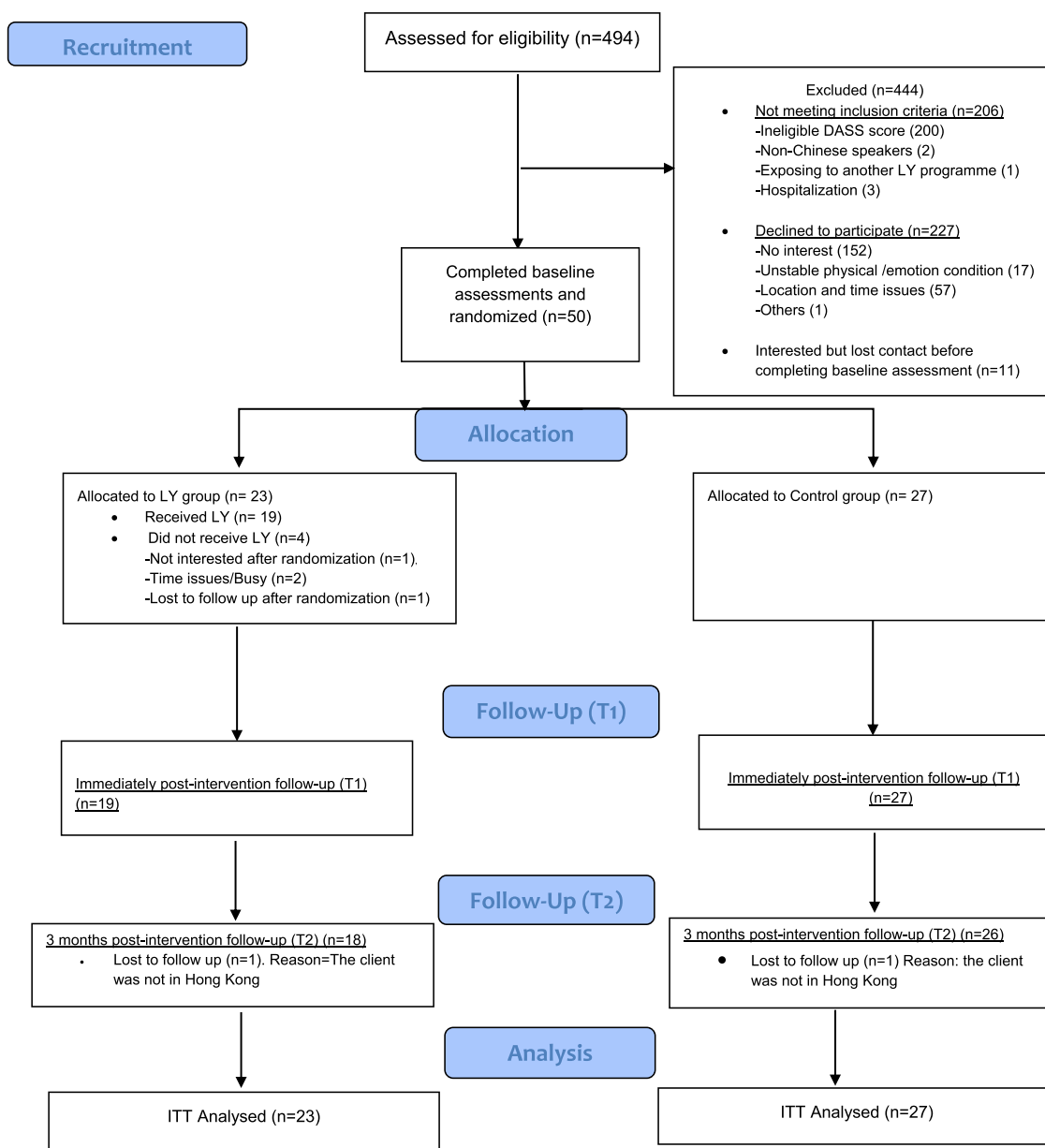


Fig. 1. CONSORT diagram.

client/patient satisfaction with a service or intervention. It consists of eight Likert scale questions scored from 1–4 and is reported to have excellent reliability (alpha coefficients range from 0.83 to 0.93) and internal consistency in patients with a variety of physical and mental health conditions (Attkisson and Zwick, 1982).

3.9. Establishing potential effects of the LY intervention on patient outcomes

Participants' levels of depression, anxiety and stress was measured using the Chinese version of the Depression Anxiety Stress Scale (DASS–21) initially developed by Lovibond and Lovibond (1995). It consists of 21 items with three subscales of seven items each (depression, anxiety and stress). Each item is scored on a 4-point Likert scale (from 0–3), with a higher score indicating more severe levels of distress. The Chinese version has been shown to have good test-retest reliability, internal consistency and convergent validity with the Chinese Beck Depression Inventory and Chinese State-Anxiety Inventory in the general population and in people with diagnosed mental illness (Oei et al., 2013; Chan et al., 2010, 2012).

The Short Form 12 item (version 2) Health Survey (SF12v2) was used to measure patients' self-reported physical (PCS-12 composite score) and mental (MCS-12 composite score) health-related quality of life (Lam et al., 2013). The Hong Kong Chinese version of the SF12v2 has demonstrated good test-retest reliability and internal consistency (Cronbach's alpha 0.67; and intraclass correlation 0.82); and high sensitivity and very high construct validity in Chinese populations (Lam et al., 2013).

3.10. Data analysis

Descriptive statistics were used to contextualise the demographic and clinical characteristics of the study population. Mann Whitney U Test and Chi-Square/Fisher Exact Test were used for comparisons of demographic/clinical characteristics and outcome measures between the two groups at baseline. Outcome analysis was performed on an intention to treat basis by comparing the changes in the outcomes from baseline to two post-tests between groups using Generalized Estimating Equations (GEE) with identity link function and AR(1) correlation

structure for the repeated measures. The GEE approach can account for intra-correlated repeated measure data and accommodate missing data that is missing at random. All statistical tests were two-sided and the significance level was set at 5%. Data were analysed by a statistician not otherwise involved in the study.

3.11. Qualitative interview data analysis

Inductive thematic content analysis was used for the interview data (Braun and Clarke, 2006). The recorded interviews were transcribed into Cantonese by the RA and cross-checked for accuracy by one Cantonese-speaking co-investigator. The transcripts were independently coded by two co-investigators. The initial codes were then discussed and combined to form main categories and subcategories. Coding/category discrepancies were resolved by referring back to the data as needed and via further discussion by the research team in order to reach agreement.

4. Results

4.1. Study participants

A total of 494 patients with a diagnosed depressive illness were identified from the patient records. Of these, 206 (41%) did not meet the inclusion criteria, mainly due to scoring too low on the DASS subscales ($n = 200$). Eleven (2%) were interested to take part, but could not be contacted to complete the baseline assessments. A further 227 (45%) potential participants declined to participate. Finally, 50 participants were randomly allocated into either the LY ($n = 23$) or TAU ($n = 27$) group after completing the baseline measurements. Please see Fig. 1 for CONSORT diagram summary of the study.

Analysis of participants' baseline demographic and clinical characteristics (Table 1) revealed no statistically significant differences between the two groups. Participants had a mean age of 46 years in the LY group and 49 in the TAU group (Range 18–60). The majority (70%) were women, living with relatives (75%) and were married (42%). A minority were employed (16%), although most (86%) had completed at least secondary school education. They had been diagnosed with depression for an average of around 4 years in the LY group and 5 years in the TAU group. One half of participants had also been diagnosed with comorbid physical illnesses. All were prescribed antidepressant medication, with just under a third (28%) receiving two different antidepressant drugs. The majority (52%) were prescribed a hypnotic, 60% were taking anxiolytics and 40% were also prescribed an antipsychotic drug. Please see Table 1 for study participants' demographic and clinical characteristics.

4.2. Feasibility of conducting a full scale RCT

The overall refusal rate of eligible participants was 78.8% (227 from 288). Of these, 66% ($n = 152$) were not interested in the intervention and 25% ($n = 57$) were unable to attend due to inconvenient group times/locations. Seventeen (7%) of eligible participants declined participation due to their mental state. Nineteen (83%) of the 23 patients randomised to the LY group after baseline measures were completed received the intervention, the most common reason for not starting the intervention was a lack of time and inconvenience of the LY group schedule.

In terms of attrition, one LY participant was lost to follow-up at the three-month point as she had left Hong Kong. All 27 TAU participants completed assessments at baseline and at T1 (post intervention) and one was lost to follow up at three-months, also due to being away from Hong Kong. The attendance rates of the 19 participants who were randomized to the LY group ranged from 1–8 sessions, with a median of 4 (mean = 4.10, SD = 2.64). Unfortunately, only two LY participants returned their completed workbooks with details of home practice. One

Table 1
Sample demographic/clinical characteristics at baseline.

	LY ($n = 23$)		TAU ($n = 27$)		<i>p</i>
	<i>n</i>	(%)	<i>n</i>	(%)	
Age (<i>M, SD</i>)	46.30	12.84	49.37	9.13	.53 ^a
Duration of depression diagnosis, in months (<i>M, SD</i>)	48.59	45.21	62.31	49.47	.19 ^a
Gender					
Male	6	(26.1)	9	(33.3)	.58 ^b
Female	17	(73.9)	18	(66.7)	
Marital status					.50 ^b
Single	7	(31.8)	4	(14.8)	
Married	8	(36.4)	13	(48.1)	
Widow/Divorced	7	(31.8)	10	(37)	
Dwelling status					.73 ^c
Living alone	4	(18.2)	7	(25.9)	
Living with relatives	18	(81.8)	20	(74.1)	
Education level (Highest qualification)					.44 ^b
No education	2	(9.1)	1	(3.7)	
Primary	3	(13.6)	8	(29.6)	
Secondary	14	(63.6)	17	(63)	
University or above	2	(9.1)	1	(3.7)	
Others (e.g. still under education)	1	(4.5)	0	(0)	
Employment status					.50 ^b
Full-time/Part time	2	(9.5)	6	(22.2)	
Unemployed	16	(76.2)	18	(66.7)	
Others (e.g. Housewife)	3	(14.3)	3	(11.1)	
Physical comorbidities					
Systemic (e.g. Hypertension)	4	(17.4)	4	(14.8)	1.00 ^c
Diabetic	2	(8.70)	6	(22.2)	.26 ^c
Chronic Pain	2	(8.70)	3	(11.1)	1.00 ^c
Hepatic (e.g. Fatty liver)	1	(4.35)	2	(7.40)	1.00 ^c
Respiratory (e.g. Asthma)	0	(0)	2	(7.40)	.49 ^c
Neurological	1	(4.35)	1	(3.70)	1.00 ^c
Endocrine	1	(4.35)	1	(3.70)	1.00 ^c
Others	2	(8.70)	2	(7.40)	1.00 ^c
No. of physical comorbidities					.47 ^b
0	12	(54.5)	13	(48.1)	
1	6	(27.3)	10	(37.0)	
2	3	(13.6)	1	(3.7)	
3 or above	1	(4.5)	3	(11.1)	
No of antidepressants					.53 ^b
1	17	(73.9)	18	(66.7)	
2	5	(21.7)	9	(33.3)	
No of hypnotics					.59 ^b
0	12	(52.2)	15	(55.6)	
1	10	(43.5)	12	(44.4)	
No of anxiolytics					.29 ^c
0	11	(47.8)	8	(29.6)	
1	9	(39.1)	17	(63.0)	
2	2	(8.7)	2	(7.4)	
No of antipsychotics					.77 ^b
0	14	(60.9)	15	(55.6)	
1	8	(34.8)	12	(44.4)	

LY: Laughter Yoga Group; TAU: Treatment as usual group.

Note: LY group demographic/clinical information missing for one to two participants.

^a Mann Whitney U Test.

^b Chi-Square Test.

^c Fisher Exact Test

* $p < 0.05$.

practiced every day for 5 to 10 min from the start of the intervention to 3 months follow-up. The other practiced LY at home on 12 occasions (for 5 to 10 min) during the month when she attended the groups. The main reason for not completing the workbooks was due to forgetfulness or lack of motivation. Some participants also expressed concerns about practicing at home, which was explored in the individual qualitative interviews.

Table 2
Examples of participant quotes by theme.

Theme	Sub-theme	Quote
What worked	Stress relief and relaxation	<p>“When interacting with each other with ha ha ha, feeling more relaxed” (LY32)</p> <p>“Teaches you the techniques of releasing the stress such as appraising positively to yourself by saying “very good very good !” ... helps people with illness to alleviate emotions ...release stress” (LY38)</p> <p>“The atmosphere is relaxing, very enjoyable., I never thought I can laugh so easily, in the past I easily get tense, sometimes now I laugh a bit more (LY4) ” (LY04)</p>
	Happiness	<p>“Being taught by the instructor and with the group are happybeing relaxed, playing together is happiness” (LY21) ...</p> <p>“I laugh very happily indeed, so freely ... I have never been so happy at home before especially in this recent year, now I can laugh happily, I feel good and blessed” (LY38)</p>
	Exercise without restrictions	<p>“When I feel unhappy, I will say “ha ha ha” to myself and become happy...”(LY23)</p> <p>“We are taught how to breath in and out and it can be practiced while we are on the bus or waiting for the bus”. (LY21)</p> <p>“The he-he-ha-ha activity can be done while walking or waiting for the bus, do it silently, people won't notice you are breathing, I can help myself without affecting others”. (LY04)</p>
	Laughing in a group	<p>“While cooking and washing, I will do “ha ha ho ho” in the kitchen, while watching TV, I will clap hands”(LY11).</p> <p>“The he-he-ha-ha activity can be done while walking or waiting for the bus, do it silently, people won't notice you are breathing, I can help myself without affecting others”. (LY04)</p> <p>“While cooking and washing, I will do “ha ha ho ho” in the kitchen, while watching TV, I will clap hands”(LY11).</p> <p>“We will act together and share our feelings in group after the event, the interaction and the exchanges with others are friendly ...I like the activity of acting as sailing boats and swinging motion ...it is fun” (LY54)</p> <p>“ one follows the other., it is a genuine laugh, not the same as the dead atmosphere at work...it gives the group an environment and the feelings of being together” (LY11)</p>
What did not work	Difficulty practicing outside the groups	<p>“I will practice at home at the beginning, especially when my emotion is bad. This made me feel relaxed and happy, I didn't have to keep things bottled up... but my sons would say I am crazy...they told me to calm myself down” (LY32)</p> <p>“I am staying at home.... in a subdivided flat and I don't even have space to practice. My children will scold me, they are old enough to call me crazy now... he will scold me...” (LY04)</p>
	Physical and mental health barriers to attendance	<p>“I fear that neighbors would think I am crazy-therefore rarely practice” (LY38)</p> <p>“I am so afraid to meet people. I am scared that the others will see me and don't want to meet anyone. I just want to hide myself. Sometimes I don't want to go anywhere... I feel very uncomfortable and tired... I don't have the mood to do it.” (LY32)</p> <p>“If I am not injured, I will attend all the sessions...I have been seeing the physiotherapist for a long time, but I was still feeling painful all the time. And then I started feeling reluctant to come” (LY21)</p>
	Childlike playfulness	<p>“I had a hospital admission and could not practice the LY” (LY06)</p> <p>“It is useless from my perspective, I find these activities to be childish. I know I should not devalue it. But when I am doing those movements, I find that to be childish” (LY57).</p>
	Negative effects	<p>“... Because she told us to return to the childhood and act like a child... this makes me resist at the beginning... I am already quite old. I have thought of whether I should return in the next session” (LY11)</p> <p>“I am feeling breathless and feeling very uncomfortable. I was feeling extremely uncomfortable on the second and third day. (LY23)</p> <p>“My heartbeat became very obviously fast. The pulse made me feel uncomfortable. I just know that I couldn't sleep well at those nights. I don't know what's going on” (LY06)</p>
What to improve	Bigger venue	<p>“The first session... I don't know the fact that it will involve so much things... I mean laughter Yoga... I am quite surprised. After doing a few acts in the first session, why is it so different (from other yoga programmes)? (LY11)</p> <p>“Better to have some introductory information about LY and better to let participants know the content of the 8 sessions” (LY57)</p>
	Realistic expectations	<p>“It would better if there are more people.. The more people the better... I don't have a specific number on that... More people can create a better atmosphere” (LY04)</p>
	Increase number of people in the groups	<p>“ It would be happier if there are more people. More people when practicing... So that we can laugh together” (LY32)</p> <p>“Apart from laughter and “happiness”, you can think of adding some songs (into the programme)... singing songs...and unleashing our desire to perform” (LY21)</p>
	Greater variation of group exercises	<p>“We were doing similar things throughout the 8 sessions, it is quite rigid..”, I mean there is nothing new. You need some variety among the activities... More movement involving four limbs in LY would be better” (LY43)</p>
	Longer program	<p>“I think the number of sessions is too little. I prefer at least 10–15 sessions because we are not familiar (with the exercise) at the beginning...Everyone does (encounter the same problem)... We are not dare to laugh at the beginning” (LY06)</p> <p>“It is good to provide a long term course for us... those with depression or those who are taking your medications... It is good for us if this programme can last longer because we our kind of people always have poor memory” (LY38).</p>

4.3. Satisfaction and acceptability of the LY intervention

The LY participants' ($n = 19$) satisfaction with the intervention (measured using the CSQ8) ranged from 16 to 30 (from a maximum of 32), with a mean score of 21.90 ($SD = 3.67$) and median of 22.0; suggesting an overall favourable level of satisfaction.

Twelve LY participants were purposively selected to attend an individual follow-up interview in accordance with the study protocol. One did not attend due to being way from Hong Kong. The eleven interviews lasted from 10 to 25 min. Content analysis of the transcripts revealed three main themes: *what worked*, *what did not work*, and *what to improve*. Thirteen sub-themes were also identified. Please see Table 2 for each theme, subtheme and associated example quotations.

In terms of positive effects of LY (“*what worked*” theme), most of the interviewees who attended more than two sessions explained that

attending the groups and practicing the exercises made them feel happy, helped them to relax and provided an opportunity to release negative emotions. Some participants also mentioned that they felt great benefit from the group interaction and sharing their feelings with others. In addition, five interviewees stated that they were able to use the deep breathing approaches and practice some basic LY exercises whilst travelling or carrying out household chores.

In relation to the “*what did not work*” theme, nine participants mentioned having difficulty in practicing laughter yoga openly (at home or in the public area) due to the small living environment in Hong Kong and fears that other people would be concerned about their mental state and label them as being “crazy”. Eight participants discussed how daily problems with their mental health (i.e. low mood/motivation) or physical health (chronic pain) prevented them from attending the groups or practicing LY on some occasions. Three

participants (who attended two or less sessions) did not enjoy or appreciate the childlike playfulness exercises that are at the core of the LY approach and indicated that they encountered difficulty in making fake laughs, especially at the beginning of the course. Three other participants also expressed that they experienced some negative effects of the LY, including feeling breathless and having an increased heart rate.

Many participants also identified some areas of the LY intervention that required improvement (“*what to improve*” theme). These included having a bigger venue, more people in the groups, a wider variety of activities and a longer programme duration. Two interviewees also mentioned a discrepancy between their original expectation of the intervention (i.e. a traditional yoga class) and the actual LY intervention (with fake laughter, playfulness and no traditional yoga positions).

4.4. Effects of the group-based LY intervention compared with treatment as usual

The outcome measure results indicated that the LY group had a statistically greater decrease in depression (DASS21 – Depression scale) than the control group from baseline to immediately following the intervention ($B = -5.123$, 95%CI: -9.527 to -0.72 ; $p = 0.023$). However, there was no statistically significant difference in the change in depression from baseline to 3-month follow-up between the two groups ($B = -2.724$; 95%CI: -7.106 to 1.658 ; $p = 0.223$).

There was also a statistically greater improvement in mental health related quality of life (MCS of SF12v2) in the LY group compared to the control group from baseline to immediately after the intervention ($B = 4.386$, 95%CI: 0.342 to 8.430 ; $p = 0.034$). Similarly to the depression scores, the improvement in mental health related quality of life was not significantly different between groups over 3-months follow-up ($B = 3.775$, 95%CI: -0.883 to 8.432 ; $p = 0.112$).

There were no statistically significant differences in changes in anxiety (DASS21 –Anxiety scale) between groups from baseline to the first follow-up ($B = -3.256$, 95%CI: -7.309 to 0.258 ; $p = 0.068$) or second follow-up ($B = -2.321$, 95%CI: -6.458 to 1.816 ; $p = 0.271$). There were also no significant differences between groups in changes in stress (DASS21- Stress scale) from baseline to the first ($B = -3.796$, 95%CI: -7.743 to 0.151 ; $p = 0.59$) or second ($B = -2.101$, 95%CI: -6.200 to 1.997 ; $p = 0.315$) follow-up points. Likewise, changes in physical health related quality of life (PCS of SF12v2) were not significantly different between the groups immediately following the intervention ($B = 0.476$, 95%CI: 1.706 to -2.867 ; $p = 0.780$) or at 3-months follow-up ($B = -2.767$, 95%CI: -6.854 to 1.501 ; $p = 0.209$).

Please see Table 3 for the estimated marginal means and standard errors of the outcome measures at all follow-up points.

5. Discussion

Despite the promising results observed post intervention, the feasibility of conducting a future large scale randomized controlled trial of

LY in the study setting using exactly the same study design and procedures is doubtful. We eventually recruited approximately 20% of eligible participants, which was below our target sample size. The main reason for lack of interest in the study related to practical problems with attending LY groups. This was primarily because we scheduled the LY groups twice a week (on weekdays) and many potential participants were unable to commit to this due to existing household and childcare responsibilities. Future studies of LY in the study setting should therefore consider improving accessibility by offering less frequent groups during the week and at weekends, or perhaps by offering four groups per week of which participants could choose two that are most convenient. Some of the eligible clients were also unfamiliar with the LY intervention and refused to take part because they feared they would be required to maintain physically strenuous yoga poses. We addressed this in the latter phases of recruitment by showing video examples of the intervention to alleviate their concerns. This strategy seemed to be effective, and therefore future studies of LY could consider utilising multi-media information sources to ensure that potential participants are very clear about the nature of the intervention, rather than just relying on discussion and written information.

On reflection, our participant eligibility criteria were also very restrictive and this appears to have been a barrier to recruitment. We specified that participants were required to have residual symptoms of depression, in addition to residual anxiety and/or stress in order to join the study. These eligibility criteria resulted in 40% of the almost 500 potentially eligible participants being excluded because they scored too low on one or more of the DASS subscales. In fact, 63 people who met the minimum symptom threshold for depression were deemed ineligible to take part because they did not have additional symptoms of anxiety and/or stress. Therefore, the feasibility of recruiting sufficient numbers for a future full scale RCT might be improved by adopting eligibility criteria of residual depressive symptoms without the requirement for other additional symptoms.

We also examined satisfaction of the LY intervention from participants’ perspectives; the median CSQ8 scores indicated a generally positive level of satisfaction and perceived usefulness of the LY intervention. In addition, the individual qualitative interviews revealed some interesting and useful information that is relevant for planning future LY interventions for people with depression. The majority of participants found that the simulated laughter and breathing exercises were very useful to help them relieve stress/tension and generally feel happier. Many participants also reported that laughing in a group setting triggered contagious genuine laughter and that attending the groups afforded them a rare opportunity to share their feelings with others. These perceived benefits seem to be consistent with the literature suggesting hypothesized therapeutic effects of LY (Bennett and Lengacher, 2008; Shaidi et al., 2010; Pan and Yeh, 2016).

In terms of the acceptability/tolerance of the LY intervention, three study participants described experiencing some discomfort relating to an increased heart rate, developing a dry mouth and feeling breathless.

Table 3
Study outcome measures of both groups at the three time points.

Outcome	Baseline		Post intervention		3 months	
	LYEstimated Marginal Mean (SE)	TAUEstimated Marginal Mean (SE)	LYEstimated Marginal Mean (SE)	TAUEstimated Marginal Mean (SE)	LYEstimated Marginal Mean (SE)	TAUEstimated Marginal Mean (SE)
Depression	27.62 (1.99)	23.48 (1.41)	23.10 (2.01)	24.07 (1.78)	24.23 (1.95)	22.81 (1.75)
Anxiety	26.87 (1.42)	22.30 (1.26)	23.78 (1.51)	22.74 (1.42)	24.17 (1.55)	21.92 (1.84)
Stress	29.62 (1.40)	24.74 (1.60)	26.19 (1.75)	25.11 (1.28)	27.34 (1.45)	24.56 (1.72)
PCS	37.35 (1.58)	36.54 (1.11)	38.54 (1.77)	37.26 (1.23)	36.26 (1.97)	38.14 (1.44)
MCS	30.60 (1.48)	35.30 (1.21)	33.93 (1.95)	34.25 (1.32)	34.84 (1.58)	35.77 (1.74)

LY: Laughter Yoga Group; TAU: Treatment as usual group.
SE = Standard Error.

PCS = Physical composite score of SF12v2; MCS = Mental composite score of SF12v2.
Depression, Anxiety and Stress subscales from DASS21.

However, none of these issues required any medical/nursing intervention. None of the previous LY studies has reported the incidence of adverse events and it is therefore impossible to ascertain if such discomfort is a common occurrence (Bressington et al., 2018). Similarly, many studies of traditional yoga for depression fail to report harms/adverse events (Cramer et al., 2013); although systematic reviews of yoga for schizophrenia (Cramer et al., 2013a) and anxiety/stress (Li and Goldsmith, 2012) concluded that there was no evidence of severe adverse events. A minority of participants ($n = 3$) reported that they found it difficult to engage with the playfulness aspect of LY and make fake laughs. It is noteworthy that these participants found this most problematic in the earlier groups, and this may suggest that there needs to be a degree of socialisation into the intervention in order to cultivate a sense of openness and remove initial inhibitions. Problems engaging with the intervention have not been reported in previous LY studies (Bressington et al., 2018), however most of these studies involved participants who had pre-existing relationships with each other (i.e. college students, care home residents and work colleagues). Whereas many of the LY group members in the current study did not know each other and this lack of familiarity might have further contributed towards any embarrassment. Future studies of LY might benefit from integrating some relationship building activities into the initial group sessions.

Although some participants were able to use the breathing exercises and less obvious LY techniques whilst in public, the majority were not able to openly practice LY whilst at home or outside. The inability to practice arose from concerns that others would view them as “crazy” because they would be overheard in the densely populated environment of Hong Kong. These fears are understandable in Hong Kong due to the prevailing stigmatisation towards mental illness reported in Chinese societies, and may be magnified because Chinese people are likely to internalize this public stigma (Kung, 2001; Mak and Cheung, 2008) and perceive a need to keep their mental illness a secret (Ow and Katz 1999). It is therefore possible that further improvements in depression and mental health related quality of life were not observed at 3 months follow-up due to the lack of home practice performed by the LY participants. While most LY studies (and other similar laughter therapy studies) have only measured outcomes immediately following the groups, there is some limited evidence that improvements in mental well-being can be maintained over time, albeit not in a study population with a diagnosed depressive illness. For example, a study involving 33 employees of a behavioural health centre reported that 15 daily sessions of LY techniques resulted in significant improvements in self-regulation, optimism, positive emotions, and social identification that were maintained at 90 days follow-up (Beckman et al., 2007).

Based on the participants’ narratives, some modifications to the intervention should be considered to enhance engagement and promote home LY practice. Data from the qualitative interviews highlight that the less obtrusive home LY exercises, such as clapping and silently/quietly chanting “ha ha, ho ho”, were regularly used by some participants, suggesting that these type of exercises may be more acceptable. As most of the participants’ concerns about using the more obvious home LY exercises related to how they may be viewed as being “crazy” by family members, this may suggest that there is a need to socialise family members into the intervention before home practice can be used. Therefore, it may be useful to encourage participants to share information about LY with their relatives, or perhaps invite dyads of participants and their relatives to attend the LY groups together. However, promoting home practice to maintain improvements in outcomes is likely to be challenging because participants’ lack of persistence with yoga-based interventions and the loss of short-term gains is a commonly reported issue, particularly in people with depression. For example, a 6 month RCT of traditional yoga for healthy older adults (Flegal et al., 2007) reported an overall class attendance rate of 77% and 64% adherence with yoga home practice, however participants with higher self-rated depression scores at baseline were statistically

more likely to drop out and less likely to engage in home practice. Similarly, a systematic review of yoga for depression (Cramer et al., 2013) reported that only five from the twelve included RCTs had acceptable rates of attrition. Some potential strategies to improve class attendance, study attrition and persistence with home practice might include providing reminders, making home practice instructions as simple as possible, rewarding attendance and offering social support/reinforcement (Flegal et al., 2007; McDonald et al., 2002; Salmon et al., 1998).

A number of potential modifications to the interventions were directly proposed by the study participants, and these may enhance the effectiveness and acceptability of the intervention. Perhaps most importantly, these included ensuring that potential participants were fully aware how the LY intervention differs from traditional yoga and including a greater variety of LY exercises/activities in the groups. Some participants also suggested that singing and/or exercise that is more physical should be built into the LY intervention. This would be potentially beneficial as some studies have previously been conducted using “Laughter Therapy”, which includes some of the simulated laughter techniques used in LY in conjunction with exercise. These studies resulted in significant improvements (immediately post-intervention) in general health, insomnia, and anxiety (Ghodsbin et al., 2015), self-rated health (Hirosaki et al., 2013), and depression/sleep quality (Ko and Youn, 2011) in the elderly participants.

The final objective of this study was to evaluate the potential effects of the group-based laughter yoga (LY) intervention on depression, anxiety, stress and health related quality of life. The results were encouraging as there were statistically greater improvements in depression and mental health related quality of life in the LY group compared to the control group immediately after the intervention. However, these statistically significant improvements were not apparent from baseline to 3 months follow-up. There were no significant differences between groups in other outcome measures.

6. Study limitations and strengths

This study has some limitations worthy of consideration. This is a feasibility study with a small sample size. It was also impossible to blind participants to group allocation, and as the outcomes measures were all self-completed, the results are heavily subject to performance and social-desirability bias. A further potential limitation is the reliance on community diagnoses of psychiatric disorders to assess eligibility (as opposed to the use of a structured diagnostic interview). In addition, the study did not involve an active comparison group intervention; therefore, there is a risk that the positive effects of the LY intervention may only relate to non-specific group effects. Despite these limitations, this study has a number of methodological strengths, including the random selection of participants, random allocation to groups and strict adherence to the study protocol.

7. Conclusion

The findings suggest that a full-scale RCT of LY as an adjunctive treatment for residual symptoms of depression could be feasible if some modifications were made to the protocol/intervention. The results also show that the intervention could be effective to reduce depression and improve mental health related quality of life immediately post intervention. Future studies of the LY intervention in Hong Kong should use an active control group intervention, adopt a less restrictive residual symptom eligibility criteria, aim to gradually socialise participants into the intervention, incorporate a greater variety of exercises in groups, teach home practice exercises that can be used unobtrusively and schedule sessions flexibly to encourage attendance.

Author statement

The study was designed by DB, WTC, MB and JM, all other authors made suggestions/comments about the protocol. Data collection was conducted by CY and facilitated by JM. SFL, KC and CW provided support for the intervention group facilitator. DB, CW, SFL, KC and CY conducted the qualitative data analysis. DB drafted the first version of the manuscript. Each author listed has made a substantial contribution to the manuscript, has read and approved the final version, and is able to take public responsibility for it.

Conflicts of interest

We declare no conflicts of interests.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.jad.2019.01.030.

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