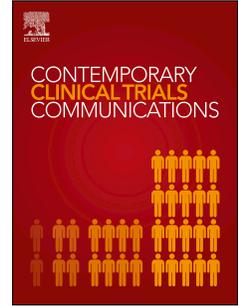# Journal Pre-proof

Prescribing laughter to ameliorate mental health, sleep, and wellbeing in university students: A protocol for a feasibility study of a randomised controlled trial

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Prescribing laughter to ameliorate mental health, sleep, and wellbeing in university students: A protocol for a feasibility study of a randomised controlled trial

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Highlights

- First study to explore the feasibility of a laughter only prescription for university students

- First assessment of the impact of laughter on psychological health and objective sleep outcomes

- A combination of wrist actigraphy and the Laughie enables clear measurements of sleep and laughter

- Provision of a detailed description of the Laughie and how to use it and prescribe it

Abstract

Objectives

This research is the first study to investigate the potential effects of a laughter prescription on both psychological health and objective sleep parameters in university students. The primary objective is to evaluate the feasibility of prescribing laughter to inform a larger randomised controlled trial. Secondary objectives are to assess if a two-week laughter prescription improves subjective and objective sleep outcomes, wellbeing, and/or psychological health outcomes.

Trial design

To assess the feasibility of a randomised controlled trial for laughter prescription in relation to sleep, psychological health, and wellbeing. Forty university students will be recruited and randomised to one of two conditions (control/experimental).

Methods

Wrist actigraphy and sleep diaries will be used to estimate sleep outcomes during a one-week baseline testing phase and across the two-week intervention. The experimental group will be shown how to record a Laughie (a one-minute recording of their joyful laughter on their smartphone) and prescribed to laugh with it three times daily for 14 days (the control group will only track sleep). All participants will complete the WHO (Five) Well-being Index, and Hospital Anxiety and Depression Scale pre- and post-intervention. The CONSORT checklist, and the Feasibility, Reach-out, Acceptability, Maintenance, Efficacy, Implementation, and Tailorabilty (FRAME-IT) framework will guide intervention planning and evaluation. Participant interviews will be analysed using Differential Qualitative Analysis (DQA).

Results

The feasibility of a two-week laughter prescription in university students and its impact on sleep, wellbeing, and/or psychological health outcomes will be assessed.

Conclusions

Zayed University Research Ethics Committee approved the study in July 2019. The research will be completed following protocol publication.

Trial registration: ClinicalTrials.gov. ID: NCT04171245. Date of registration: 18 October, 2019

Keywords: feasibility study; randomised controlled trial; laughter prescription; sleep; psychological health; university students; wellbeing.

Abbreviations: UAE=United Arab Emirates; WHO=World Health Organization; CBT=Cognitive Behavioural Therapy; RCT=Randomised Controlled Trial; PI=Principal Investigator; HADS=Hospital Anxiety Depression Scale; PSQI=Pittsburgh Sleep Quality Index; TST=Total Sleep Time; SOL=Sleep Onset Latency; SE=Sleep Efficiency; WASO=Wake After Sleep Onset; PSG=Polysomnography; FRAME-IT=Feasibility, Reach-out, Acceptability, Maintenance, Efficacy, Implementation, and Tailorability; IQR=Interquartile Range; ANCOVA=Analysis of Covariance; ITT=Intention To Treat; DQA=Differential Qualitative Analysis; BPSE-B=Biological, Psychological, Social and socio-economic, Environmental, and Behavioural.

Introduction

The United Arab Emirates (UAE) national drive to promote happiness has highlighted the need to nurture health and wellbeing amongst its population[1]. A systematic review revealed the prevalence of depression in the UAE to range 12.5-28.6%, with females more affected[2]. The World Health Organization (WHO), estimates the global prevalence rate of depression to be 4.4%[3]. Thus, methods for reducing and preventing depression amongst the UAE population has been a primary focus. Despite the social stigma surrounding help-seeking behaviours pertaining to mental health in this region, 91.4% of 70 Emirati female students reported that they would be open to obtaining help for psychological issues[4]. A study in Al Ain, the fourth largest city in the Emirates, reported 22% of 700 university students suffered with depression[5]. Two studies have further identified elevated levels of depression in UAE university students[6,7]. Current, ongoing research amongst Zayed University students has also found higher-than-average levels of depressive and anxiety symptoms, as well as sleep inconsistency (unpublished data). Psychological conditions have multiple adverse effects including academic outcomes, home management, personal relationships, and social life[8]. Moreover, mental health also correlates with poor sleep in students[9]. Hence, there has been increasing interest in exploring ways to tackle mental health[10].

Sleep deprivation is widespread amongst university students[9,11], and it is detrimental to student learning[11,12], and health[13]. A significant association between sleep quality, and depression, anxiety and stress has been recently identified in Saudi Arabian students[14]. Within the Gulf States, programmes have been recommended to motivate student health responsibility[15]. A systematic review[16] demonstrated that sleep improvement is best achieved through cognitive behavioural therapy (CBT) and, whilst this method has a strong evidence-

base, it requires trained practitioners and additional resources. It is therefore unlikely to be as cost-effective as a resource which is intrinsically embedded and readily accessible.

Laughter is a natural, free, innate behaviour associated with a range of health outcomes across the lifecycle[17]. A meta-analysis of ten randomised controlled trials (RCTs) of laughter and humour interventions showed they significantly decreased adult depression, anxiety, and improved sleep quality[18]. The Laughie (a one-minute recording of the user's joyful laughter on their smartphone) was conceived as a convenient way to prescribe self-induced laughter. Users record their Laughie and are prescribed to laugh with it. The Laughie doubles as a timer and prompt and can be used alone or with others. Initial research demonstrated a 16% significant increase in wellbeing when prescribed three times daily for seven days[19]. Our protocol describes the first study to examine the impact of the Laughie, a laughter-only prescription, on mental health, wellbeing, and objective sleep behaviour.

Objectives

The main objective is to assess the feasibility of the Laughie for two weeks amongst university students residing in the UAE. If the Laughie demonstrates feasibility, the following secondary objectives will be assessed:

1. Subjective sleep outcomes

2. Objective sleep outcomes

3. Overall subjective wellbeing, as well as specific aspects of wellbeing

4. Psychological health outcomes including symptoms of depression and anxiety

Materials and Methods

A feasibility study will be undertaken using a mixed-methods approach. First, a randomised controlled design with pre-and post-intervention measures will be conducted. Qualitative post-intervention interviews will also be completed. The study has been approved by the Zayed University Ethics Committee (ZU18_102_F) in July 2019 and will be carried out in accordance with the Declaration of Helsinki. The research will be completed once the protocol is published.

The principal investigator (PI; TA) and co-PI (FGS) will conduct the research at Zayed University, Abu Dhabi campus. Two external collaborators from the University of Derby (GG & DS) will serve as co-investigators. Independent quantitative analysis will be conducted by a collaborator from the University of Birmingham (OMO) who will be blinded to the group status of enrolled participants. Students will be recruited to the study for voluntary participation from Zayed University, Abu Dhabi.

Participant recruitment

As this is a feasibility study, we plan to recruit 40 participants: 20 randomised to the control group (no laughter prescription), and 20 to the experimental group (two-week laughter prescription). Although some have suggested that 12 participants in each group is adequate for pilot/feasibility studies[20], we selected a greater number based on prior research efforts where the recommendation to detect a small standardized difference at 80% power is 20 participants per arm[21]. Due to sex segregation, and a predominantly female student population within Zayed University, the intervention will initially be tested amongst female students. Recruitment will take place during lunch breaks, by word-of-mouth, and by giving short

presentations within classes in order to recruit outside of the Psychology major programme. Participation criteria are detailed in Table 1. Pregnant women and/or those with diagnosed psychological disorders will be permitted to participate if they are able to provide an approved medical note from their physician.

Table 1: Inclusion and exclusion criteria

Type	Details
Inclusion	Personal ownership of a smartphone; registered student at Zayed University; 18-50 years; female.
Exclusion	Chronic health conditions (cardiovascular disease, respiratory disease, cancer, type 2 diabetes mellitus); deafness; non-English speakers; inability to provide written informed consent.

Those who express an interest in this intervention will be sent study-related information by email explaining the research purpose and method, participant anonymity, and the right to withdraw at any time during the intervention. If the student expresses an interest in participation, the first study visit will be arranged.

Intervention description and timing

During this two-armed intervention all participants will be given wrist actigraphy and a seven-day sleep diary to complete to gather baseline sleep data. Thereafter, sleep will be monitored with wrist actigraphy and sleep diaries for a further two weeks during the intervention period. The control group will receive no intervention but will be invited to take part in the Laughie intervention upon completion (waitlist control). Participants randomised to the experimental group will be shown how to record a Laughie (one-minute of their joyful laughter on their smartphone) and will be prescribed to laugh with it three times a day for 14 days with an

option to reduce to twice a day in week two. All participants will attend meetings with one or both of the PIs. The following activities and visits will be completed:

Visit one: The PI provides study-related information and informs potential participants that non-adherence to the study protocol and/or failure to attend a mutually agreed study visit will result in them being excluded from the study. Those who express willingness to participate will be asked to provide written informed consent. The participant will then be asked to complete four questionnaires: 1) demographics and screening questionnaire; 2) Hospital Anxiety and Depression Scale (HADS)[22]; 3) WHO (five) wellbeing index[23]; and 4) Pittsburgh Sleep Quality Index (PSQI)[24].

Participants who are eligible to proceed after completion of the screening questionnaire will be provided with wrist actigraphy, a wearable and validated sleep monitor. A seven-day sleep diary will also be issued along with completion instructions to obtain baseline sleep data. Participants will return after one-week for the next visit.

Visit two: Participants will be randomised to one of two groups (control/experimental). Those in the control group will be re-issued with wrist actigraphy and two seven-day sleep diaries to complete which will be returned at visit three. Participants randomised to the experimental group will be taught about self-induced laughter and smart laughter, i.e. laughing in a smart way, for a smart reason, on a smartphone (Figure 1). They will be shown how to record a Laughie: a one-minute recording of their joyful laughter on their smartphone. A video created by the PIs to support participant learning and including examples of audio and audio-visual Laughies will be shown. The PI will then demonstrate how to laugh with a Laughie, by laughing along their own Laughie for the full one-minute. A silent Laughie will also be demonstrated, whereby minimal noise is made; this is designed as a substitution only in exceptional cases when it may not be socially acceptable to laugh, i.e. when in a public place,

or if the participant experiences common cold symptoms. Participants will also be provided with checklists to complete across the two-week intervention period.

Figure 1: Smart laughter techniques and instructions for recording and using the Laughie

Note. Instructions for the experimental group: 1. Your recording should sound like your natural joyful and playful laughter. If it doesn't, practice and record another Laughie! 2. Try to make the Laughie an enjoyable experience! You can add visual props (e.g. a mirror – laughing in front of a mirror), gestures (e.g. moving your arms, or legs, as well as sitting); mental aspects (e.g. thinking about joyful or amusing things, or using humour and jokes to help you to laugh); or social (e.g. laughing together with someone else while using your Laughie). 3. This is a new way of laughing and for some might be easier than others. Practice can help. 4. Because you will be laughing alone, for all or some of the time, it is good to find a reason to do it! Reason may include for health, happiness, joy, humour, exercise, relaxation, meditation, and energy. Based on and adapted[19]

The participant will then be asked to record their own Laughie on their smartphone, either as an audio, or an audio-visual Laughie (i.e. using their smartphone to make a video of themselves laughing). The PI(s) will support this process by smiling and encouraging the participant. After recording, the participant will complete the Laughie Creation Questionnaire to document their experience, and, after providing consent, send a copy of their Laughie to the

PI's smartphone. If the participant feels unable to record their Laughie in the presence of the PI(s), they will be told to practice and record it in their own time and send it later to the PI as evidence that it has been completed. Once the participant has recorded a Laughie they are happy with, they do not need to record more. They will be prescribed to laugh with their Laughie three times a day for the first week (morning, lunch, and afternoon), and at least two times a day in the second week of the intervention - always for the full one-minute. They will be told to try to laugh with it for at least 30 seconds if, for any reason, one-minute is not possible. Participants will be instructed to laugh alone with their Laughie at least once daily throughout the intervention. The other times they can either laugh alone or with others. They will be told to discontinue a Laughie if there is any discomfort or pain and re-commence only when feeling better. Participants will be advised to record this on the checklist and, if they have questions or concerns during the intervention, to contact the PI(s).

Laughie checklists for the 14-day laughter prescription will be administered and completion instructions will be given. Participants will be asked to complete the checklist after each Laughie has been performed (three per day in the first week, and at least two per day in the second week). A questionnaire for participants to complete following the two-week laughter prescription will be distributed surrounding the users experience and feasibility of the Laughie.

Visit three: Participants will return wrist actigraphy and sleep diaries. Participants in the experimental group will return their Laughie Checklists. All participants will then be asked to complete the same three questionnaires that were completed at baseline (HADS, WHO-5 wellbeing index, and PSQI). Participants will be thanked for their participation, and invited for an interview, either to discuss their experiences with the sleep equipment, or with the Laughie, as appropriate. For those not wishing to undertake a face-to-face interview, data from the written questionnaire about experiences and feasibility of the Laughie will be used.

As part of the debriefing process, participants will be provided with contact information for Zayed University counselling centre, which will be particularly important for participants who were characterised as 'abnormal' cases for anxiety and depressive symptoms (based on the HADS tool).

Interviews and follow-up

Interviews will be conducted in person, or online. They will be recorded and written up verbatim. A short questionnaire will be sent by email to those in the experimental group to track their perceptions two months after completion of the intervention.

Measures used

Eleven measures will be administered to track and assess this feasibility study before, during, and after the intervention, as detailed below (also see Table 3).

1) A *demographics/health questionnaire* will obtain information concerning laughter habits, sleep habits, and health conditions (used to screen for exclusion criteria).

2) The *Hospital Anxiety and Depression Scale* (HADS)[22] will be used to assess symptoms and severity of anxiety and depression. The HADS is a widely used tool and has been previously validated and assessed for reliability amongst Asian students[25]. It is comprised of 14 items in total, seven pertaining to anxiety and the remaining seven to depression. The questionnaire is commonly used and response options (0, 1, 2, 3) are totalled for each condition to give a score of 0–21 for each outcome which is then categorized as 0-7 to indicate 'normal' levels; 8-10 suggest a 'borderline' case, and 11-21 denotes an 'abnormal' case.

3) The *WHO (five) Well-being Index*[23] contains five items pertaining to wellbeing. Response options (1, 2, 3, 4, 5) are totalled to give a raw score for the five scores ranging from 0-25,

with 0 indicating the worst, and 25 the best wellbeing. Scores below 13 indicate poor wellbeing. It is a widely used non-invasive tool with high clinimetric validity[26].

4) The *Pittsburgh Sleep Quality Index* (PSQI)[24] will be used to assess overall sleep quality. The instrument has been previously assessed for reliability and validated in undergraduate students[27]. The tool is comprised of seven sleep domains (duration, disturbance, latency, dysfunction, efficiency, quality, medications). Each of the domain scores (0-3) are totaled to derive a global sleep quality score which ranges from 0-21. This can then be further dichotomized where >5 suggests 'poor sleep quality', and a score of ≤5 denotes 'good sleep quality'.

5) *Wrist Actigraphy* will be used to objectively estimate a range of sleep parameters including total sleep time (TST), sleep latency (SOL), sleep-wake timings, sleep efficiency (SE), wake after sleep onset (WASO), number of night awakenings and average length of night awakenings. The GT3X+ (ActiGraph, FL, USA) actigraph will be used in the study and has been previously validated against polysomnology (PSG – gold standard sleep measure) for TST, WASO and SE[28]. Participants will wear the device on their non-dominant wrist. Wrist actigraphy is triaxial accelerometry which detects and records movement. Data is downloaded and scored using the supporting manufactures software (ActiLife version 6.13) and sleep scoring is based on validated algorithms for adults[29]. Sleep-wake timings will be scored in 60-second epochs at the end of the study. Data will be de-identified and the researcher will be blinded to the participants group randomisation.

6) *Sleep diaries*, completed by the participants every evening and morning, will be used to monitor subjective sleep-wake behaviour, including napping. The following information is recorded: lights out (time attempted to sleep), time fell asleep, time woke, time got out of

bed, and tap times. The information will also be used to support sleep-wake actigraphy scoring.

7) A *Laughie Creation Questionnaire* will be administered once the participant has recorded their Laughie to gather information surrounding their experience. Questions include 'I agree to sending my Laughie to the researcher'; 'Are you happy with your Laughie?', 'How easy was it to record your Laughie?'.

8) *Laughie Checklists* will be provided for completion following each Laughie usage. After laughing with their Laughie, participants will record whether they laughed for the full one-minute. Participants will also be asked how they felt immediately after completing their Laughie. Questions include 'I laughed for one-minute', 'I laughed for at least 30 seconds', 'I laughed for less than 30 seconds', and 'I enjoyed my Laughie' and 'I felt more cheerful/better afterwards' (with responses: strongly agree to strongly disagree).

9) The *Laughie Interview Questionnaire* will explore participant experiences of the Laughie and participants will be invited to participate in a face-to-face interview with the co-PI (FGS) about their experiences of using the Laughie. Participants who do not wish to attend an interview will be asked to complete a questionnaire, provided to all participants with the Laughie Checklists, in writing. Questions will be aligned to pre-defined constructs pertaining to Feasibility, Reach-out, Acceptability, Maintenance, Efficacy, Implementation, and Tailorability (FRAME-IT)[30] (see Table 3). Examples include: 'What was your overall experience using the Laughie?'; 'Do you feel the Laughie was effective in increasing your wellbeing, and if so how?' and 'Did you maintain usage as instructed?'.

10) The S*leep Equipment Questionnaire* will explore participant experiences of the wrist actigraphy and sleep diary completion in a one-to-one interview between the participant and the PI (TA). Questions will include 'Did you find the equipment practical?' and 'Do

you think the equipment could be adapted for practical reasons or comfort and if so, how?' These questions were also designed around the FRAME-IT model[30].

11) A *Follow-up Survey* will be sent to participants in the experimental group after two months to gain insight into their perceptions of the medium-term effects of the Laughie prescription. The survey will include both open and closed questions such as 'Are you continuing to use the Laughie?'; 'How do you look back on your experience of the two-weeks?'; 'Do you plan to use the Laughie in the future?'

Table 2: Measures used to evaluate intervention effects on sleep and psychological health

No.	Name of Measure	Pre	During	Post
1	Demographic questionnaire	√		
2	Hospital Anxiety and Depression Scale (HADS)	√		√
3	WHO (five) Well-being Index	√		√
4	Pittsburgh Sleep Quality Index (PSQI)	√		√
5	Wrist Actigraphy		√	
6	Sleep Diary		√	
7	Laughie Creation Questionnaire[1]		√	
8	Laughie Checklist[1]		√	
9	Laughie Interview Questionnaire[1]			√
10	Sleep Equipment Questionnaire			√
11	Follow-up Survey[1]			√

(Header: "When applied in intervention" spanning Pre / During / Post)

[1]Experimental group only.

Evaluation framework

The Feasibility, Reach-out, Acceptability, Maintenance, Efficacy, Implementation, and Tailorability (FRAME-IT)[30] framework will be used to support the planning and evaluation of the intervention. Each FRAME-IT construct was pre-defined to guide the intervention (see Table 3) to evaluate the feasibility of, adherence to, and impact of the Laughie prescription and the sleep equipment. Overall intervention feasibility will be guided by these measures.

Table 3: Intervention planning and evaluation using FRAME-IT

Constructs	Research-focused construct definition	Measures for evaluation (see Table 2)
Feasibility	Overall intervention: Intervention logistics, delivery, recruitment, and adherence to protocol	1-11
	Prescribing laughter: Laughie creation; technical ease; two-week laughter prescription	7, 8 & 9
	Sleep equipment usage	10
Reach-out	Potential users; populations of Laughie	1, 9 & 11
Acceptability	Overall experience of Laughie; solo laughter; two-week prescription	7, 8, 9 & 11
	Use of sleep equipment	10
Maintenance	Laughie usage: fidelity, techniques, motivation	7, 8, 9 & 11
	Use of sleep equipment	5, 6 & 10
Efficacy	Laughie ability to elicit laughter	8 & 9
	Laughie ability to increase wellbeing	3, 8, 9 & 11
	Laughie ability to increase mental health	2, 8, 9 & 11

	Laughie ability to improve sleep	4, 5, 6 & 10
Implementation	Demonstration of Laughie; support	9
	Demonstration of sleep equipment; support	10
	Implementation on a larger scale	2, 3, 4, 7, 8, 9, 10 & 11
Tailorability	Laughie customization (design); personalisation (usage); current and future	7, 8, 9 & 11
	Sleep equipment	10
	Refinement for extended testing	2, 3, 4, 7, 8, 9, 10 & 11

Randomisation and allocation concealment

Consented eligible subject will be randomly allocated to either receive laughter prescription or the control group. Allocation will be made in a 1:1 ratio via a web-based system that uses a computer-generated randomisation list with variable block sizes (2 and 4). The allocations are computer generated in Stata (version 15.0) by the trial statistician and to ensure allocation concealment, the trial coordinating team and investigators have no access to this list.

Analysis

Data will be expressed as frequencies and percentages for categorical variables, mean and (±) standard deviation for continuous variables or as median accompanied by interquartile range (IQR) for skewed continuous variables, as appropriate. Sleep data (actigraphy and sleep diary) between groups at visit 2 will be compared using linear regression adjusting for a range of potential confounders including demographic data, as well as psychological health and wellbeing scores from the reliable and validated tools administered pre-intervention. Change in HADS, PSQI and WHO wellbeing index will be compared between groups by using

analysis of covariance (ANCOVA) models, adjusting for covariates and the values at baseline. As this is a feasibility study, no formal statistical hypothesis testing will be conducted and only effect sizes and 95% confidence intervals will be provided. All analyses will be done using the intention-to-treat (ITT) method and will be carried out in Stata (Version 15, Stata Corp., College Station, Texas).

Qualitative analysis will be undertaken, surrounding use of the Laughie as well as the sleep equipment, using Differential Qualitative Analysis (DQA)[31]. DQA prioritises the identification and analysis of individual variation in experiences, perceptions, and outcomes. Data is considered at both the individual and group level and this draws out information that may facilitate intervention refinement in preparation for a larger randomised control trial.

Discussion

Psychological health, wellbeing, and sleep amongst student populations is particularly imperative to understand in order to minimize further exacerbation of such issues. Exploration of cost-effective, natural, and convenient ways to prevent, alleviate, or reduce these health problems is therefore of widespread interest, particularly in the UAE which has a higher prevalence of psychological conditions compared to global estimates. Our novel study is the first of its kind to draw upon expertise across the disciplines of sleep (TA) and laughter (FGS & GG). The full intervention, or elements of it, may be appropriate for consideration within a range of university environments.

Laughter and humour can have wide-ranging Biological, Psychological, Social and socio-economic, Environmental, and Behavioural (BPSE-B) benefits on personal development throughout the lifecycle[17]. Although laughter and humour are often viewed as spontaneous

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social activities, both can be trained and self-induced solo activities. This enables them to be intentionally used for benefit. Humour and laughter may or may not occur together; the Laughie was conceived to be used without the need for humour, however this is not to say that it must be used without humour.

The link between laughter, improved sleep and positive psychological outcomes has previously been demonstrated, however more evidence is needed, hence our research. In the meta-analysis of ten RCTs exploring laughter and humour, sleep quality was only reported in two of the studies, and neither measured objective sleep outcomes[18]. Moreover, no study indicated if, or how much, participants laughed, and many also involved a range of exercises potentially confounding results. Laughter therapies such as laughter yoga by definition involve other exercises, and also tend to occur in group formats which can facilitate laughter making it difficult to accurately measure the impact of laughter itself on outcomes[32]. The Laughie laughter prescription avoids these issues: only laughter is involved, thus enabling its impact to be more easily measured.

Laughter is predominantly physiological (humour is predominantly cognitive), and as such can be viewed as an exercise in itself. The Laughie was created as a quick and convenient way to laugh alone at a time or location amenable to the user, without the need to join a group thus giving an alternative to people. It enables the user and the prescriber (be it a doctor or a researcher) to better measure how long the user laughed for (the instructions are to laugh for the full minute). As it is not so easy to laugh alone the purpose of the Laughie (i.e. the one-minute recording of the user's natural and joyful laughter on their smartphone) is to support self-efficacy and encourage people to manage their wellbeing. The user knows they can laugh for the full minute as they have done it before. Laughing along with one's own laughter acts as a prompt, and user feedback found it can give the impression that you are not laughing alone, which can also be contagious. The Laughie also acts as a timer. Currently the Laughie

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is a self-created tool recorded on a smart phone using inbuilt software; a future Laughie App or eHealth application can be envisaged.

Self-induced laughter, especially done alone, can be challenging, and four smart laughter techniques to support Laughie usage were formulated (see Figure 1) following participant comments: 1) Natural is best; 2) Enjoy it your way; 3) Train to gain; 4) Laugh for a reason. Enjoying it your own way may include using humour if it is needed to trigger laughter: the goal of the Laughie is not to exclude humour, but rather to not have to rely on it to laugh. The Laughie may even induce humour. The concept of the Laughie is simple, and the theory that underpins it is grounded in research evidence (Gonot-Schoupinsky & Garip, 2019), nevertheless the communication of Laughie usage is more complex. Our research will investigate how the Laughie is perceived in a student population, which may enable it to be better communicated in preparation for a larger randomised control trial.

Conclusions

Our research will provide insight into the feasibility of prescribing laughter, using the Laughie, to university students residing in the UAE. Data analysis will reveal whether a two-week laughter prescription can improve psychological health, sleep, and wellbeing outcomes amongst the student sample. Depending on the results, it may be appropriate to potentially refine this protocol for wider testing. Should our study demonstrate that the Laughie is feasible within the population tested, results from our secondary objectives will be used to better inform a larger trial in academic and other settings within the UAE, Gulf States, and beyond.

Trial registration:

ClinicalTrials.gov. ID: NCT04171245. Date of registration: 18 October, 2019

Competing Interests Statement

There are no conflicting interests to declare.

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CRediT roles: Conceptualization FGS, TA; Data curation FGS, TA; Formal analysis OMO, FGS; Funding acquisition TA; Investigation FGS, TA; Methodology FGS, TA; Project administration TA; Resources TA; Software TA, OMO; Supervision TA, GG, DS; Validation FGS, TA, OMO; Visualization FGS, TA; Roles/Writing - original draft FGS, TA; Writing - review & editing FGS, TA, GG, DS, OMO.

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<u>Highlights</u>

- First study to explore the feasibility of a laughter only prescription for university students

- First assessment of the impact of laughter on psychological health and objective sleep outcomes

- A combination of wrist actigraphy and the Laughie enables clear measurements of sleep and laughter

- Provision of a detailed description of the Laughie and how to use it and prescribe it

AUTHOR DECLARATION

1) We wish to confirm that there are no known conflicts of interest associated with this publication and there has been no significant financial support for this work that could have influenced its outcome.

2) We confirm that the manuscript has been read and approved by all named authors and that there are no other persons who satisfied the criteria for authorship but are not listed. We further confirm that the order of authors listed in the manuscript has been approved by all of us.

3) We confirm that neither the entire paper nor any of its content has been submitted, published, or accepted by another journal. The paper will not be submitted elsewhere if accepted for publication in the Journal.

4) We confirm that we have given due consideration to the protection of intellectual property associated with this work and that there are no impediments to publication, including the timing of publication, with respect to intellectual property. In so doing we confirm that we have followed the regulations of our institutions concerning intellectual property.

5) We confirm that any aspect of the work covered in this manuscript that has involved either experimental animals or human patients has been conducted with the ethical approval of all relevant bodies and that such approvals are acknowledged within the manuscript.

6) We understand that the Corresponding Author is the sole contact for the Editorial process (including Editorial Manager and direct communications with the office). He/she is responsible for communicating with the other authors about progress, submissions of revisions and final approval of proofs.

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