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A Protocol for a Phase-II Trial to Evaluate the Effect of a Mindfulness Intervention via a Mobile Application on Resident Physicians' Burnout

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Abstract:

***Background**: Burnout is a highly prevalent occupation-related syndrome that impacts both physicians and patients. Resident physicians face unique challenges and stressors during their training, causing burnout, which affects the quality of care, patient outcomes, and the physicians' well-being. Also, mitigation of physician burnout creates a resilient future physician workforce. Mobile-based mindfulness interventions showed promising results in reducing physicians' burnout. This paper describes the rationale and design of a first global multi-centered, prospective, randomized control study to assess the impact of mobile-based mindfulness on resident physician burnout.*

***Methods:** We plan to conduct a multicenter, cluster-randomized, two-arms (1:1 ratio), open-label clinical trial. Institutions will be randomly assigned to the use of the Smiling Mind app or a dummy app. Participants will be reassessed at 30 and 60 days for the 3 aspects of the Maslach Burnout Inventory Scale (MBIS). The primary outcome for analysis is the emotional exhaustion aspect of the MBIS at 30 days. A linear mixed regression model with adjustments for clusters will be used.*

***Discussion:** Burnout is a major issue especially among the particularly vulnerable and time-constrained group of physicians-in-training. Mindfulness-Based Stress Reduction programs are time-consuming. This study will offer the opportunity to investigate the effect of a brief mobile-based mindfulness intervention on resident physicians' burnout*

***Keywords:** Mindfulness-based intervention, Professional Burnout, Maslach Burnout Inventory Scale, Smiling Mind, Mobile Applications, Clinical Trial.*

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Abbreviations

MBSR: Mindfulness-Based Stress Reduction
MBI: Mindfulness-based intervention
RCT: Randomized controlled trials
T0 (baseline), T1 (after 30 days), T2 (after 60 days)
MARS: Mobile App Rating Scale
MBIS: Maslach Burnout Inventory Scale
PI: Principal investigator

INTRODUCTION

Physician burnout is an occupational syndrome due to a maladaptive chronic stress reaction characterized by feelings of exhaustion, emotional disconnect or cynicism related to one's occupation, and a reduced sense of accomplishment at work (Maslach & Jackson, 1981). The prevalence of this syndrome is variable, with up to 60% of healthcare professionals reporting they

have experienced burnout at some stage in their careers (Felton, 1998).

Physician burnout can have a serious negative impact on physical, emotional, and mental health, and can also lead to substance abuse (Salvagioni et al., 2017). Professionally, burned-out physicians report reduced job satisfaction and decreased productivity (Bridgeman, Bridgeman, & Barone, 2018). Moreover, burnout has been correlated with reduced quality of the care provided by affected physicians, increased risk of patient safety issues, and poor patient satisfaction scores (Panagioti et al., 2018). On the financial front, physician burnout is estimated to cost 4.6 billion USD per year due to reduced clinical hours and physician turnover (Han et al., 2019).

A global meta-analysis published in 2019 estimated a 51% aggregate prevalence of burnout in resident physicians of all specialties (Low et al., 2019). Residents in training are exposed to a variety of unique stressors, including long working hours, time management issues, poor interpersonal and coping skills, and challenging job situations (Ishak et al., 2009). Hence, identifying interventions to mitigate burnout in resident physicians is imperative.

Mindfulness practice, the ability to pay attention to the present moment, feelings, thoughts, and experiences without judgment, and its effect on reducing burnout levels has been previously studied among physicians, with varied results (Ludwig & Kabat-Zinn, 2008; Verweij, van Ravesteijn, van Hooff, Lagro-Janssen, & Speckens, 2018; West, Dyrbye, & Shanafelt, 2018).

The Maslach Burnout Inventory (MBI) questionnaire is a commonly used tool to measure job burnout. According to Schaufeli and his colleagues, MBI had been used in 93% of the journal articles by the end of the 1990s. This score was validated across cultures and occupations. (Doulougeri, K., Georganta, K., & Montgomery, A.,2016)

Mindfulness-Based Stress Reduction (MBSR) is the most popular yet time-consuming 8-week mindfulness-based intervention (MBI) (Creswell, 2017). Recently, the dramatic rise in internet and smartphone access across the globe has switched the landscape of MBI to smartphones and online-based programs (Choo & Burton, 2018; Huberty et al., 2019; Plaza, Demarzo, Herrera-Mercadal, & García-Campayo, 2013; Mani et al, 2015; Moberg et al, 2019; van Emmerik, Berings & Lancee, 2018).

Few randomized controlled trials (RCT) have examined the effect of mobile-based mindfulness intervention (Flett, Hayne, Riordan, Thompson, & Conner, 2019; Huberty et al., 2019; Moberg, Niles, & Beermann, 2019; Spinelli et al., 2019). These previous reports have found significant reductions in stress, depression, anxiety, and burnout symptoms among mindfulness users. Additionally, significant improvements have been observed in resilience, self-efficacy, and self-compassion. These differences between the intervention and control groups suggest that mobile mindfulness interventions are effective on reducing distress and burnout levels among diverse groups. However, no RCT assessing this strategy has been implemented in resident physicians, a group that might particularly benefit from this practice due to their high prevalence of burnout.

The lack of mobile-based mindfulness intervention RCT in residents highlights the need for a high-quality, randomized study, including a substantial number of residents from several countries and different specialties. This study offers the framework to evaluate the effectiveness of a mobile-based mindfulness intervention on their burnout levels in a global multinational RCT.

Primary and Secondary Objectives

Primary Objectives:

1. To assess the impact of a 30-day, mobile-based, mindfulness intervention on residents' emotional exhaustion aspect of MBIS when compared to a dummy app.

Secondary Objectives:

1. To demonstrate the impact of a 30-day mindfulness program on depersonalization and reduced personal accomplishment scores at 30 days
2. To assess the change in all three aspects of MBIS at 60 days.
3. To demonstrate the sustained benefit of intervention at 60 days.
4. To assess the change in the MBIS category at 30 and 60 days.

MATERIALS AND METHODS

Trial Design

The trial is designed as a phase-II, prospective, cluster-randomized, controlled, open-label, multicenter trial with two parallel groups and a 1:1 allocation ratio to match our primary and secondary outcomes. The two groups will be randomly assigned to the intervention arm (residents with Smiling Mind mobile application)

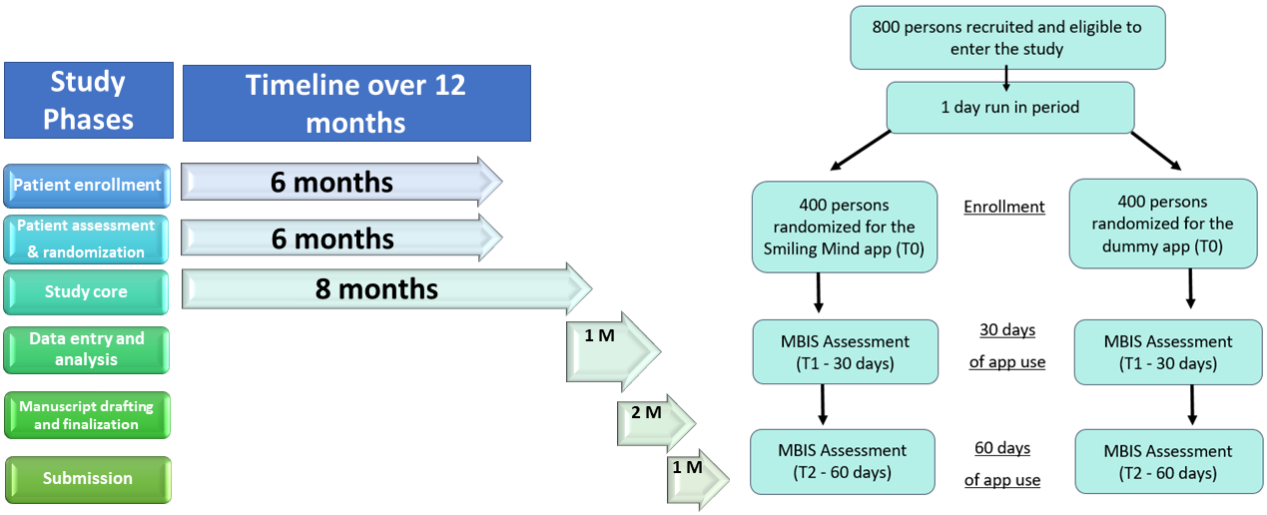

Figure 1. Flowchart for the timeline and the trial design

or the control arm, in which the subjects will use a mobile-based dummy application (Figure 1) The comparison between groups will be based on the Emotional aspect of the MBIS for burnout after 30 days to assess the primary outcome. Also, the secondary outcomes (i.e. impact of a 30-day mindfulness program on the other aspects of the MBIS, and assessing burnout at 60 days demonstrating sustained effect) will be measured by asking the participants to fill the MBIS at three-time points: T0 (baseline), T1 (after 30 days) and T2 (after 60 days).

Mobile application selection

The mobile app-based mindfulness intervention was chosen as the use of mobile phones has grown exponentially in the past decade. Mobile applications are easily accessible to the public and can be used in each participant's free time. In a study conducted by Mani et. al (2015), twenty-three mindfulness applications were reviewed and compared based on the Mobile App Rating Scale (MARS). MARS is a standardized multidimensional tool for the quality rating of health applications. It evaluates the apps based on the following four broad categories: engagement, functionality, aesthetics, and information quality. The results yielded a median MARS score of 3.2 out of 5.0, with the top five scores being for Headspace (4.0), Smiling Mind (3.7), iMindfulness (3.5), and Mindfulness Daily (3.5) (Mani et al., 2015). The Smiling Mind App was selected for the intervention in our trial since it fulfilled the desired characteristics, and it is free of cost (unlike Headspace), easy to use, downloadable for offline use, and offers a wide variety of meditation programs targeted for specific areas such as stress, attention and concentration, wellbeing, and performance.

Choice of the control group

The control group will use a dummy mobile application to mitigate the placebo effect. The dummy application will contain simple educational videos about burnout, however, it won't contain any intervention activities. Participants must use it for at least 15 minutes daily and the dummy application will be able to track the participants' use in minutes to monitor adherence. The control group will be evaluated at the same time points as the intervention group using MBIS.

Outcome Measure:

1. The Maslach Burnout Inventory Scale (MBIS), a commonly used tool, will be used to measure burnout. MBIS is a validated questionnaire that is easy to perform and takes only around 10 to 15 minutes to complete (Maslach, C., & Jackson, S. E, 1981).
2. The MBIS consists of 3 dimensions: emotional exhaustion, depersonalization, and personal achievements and will generate 3 scores identifying subjects with low, moderate, or severe burnout. Each one of the 3 dimensions of the MBIS will be measured separately, but only the emotional exhaustion aspect will be used to assess our primary outcome.
3. The use of the emotional exhaustion aspect of MBIS solely to measure burnout has been proposed by Schaufeli and other researchers (Dyrbye, West &

Shanafelt, 2009; Schaufeli et al., 2001) as a measure of burnout and has been used frequently in the literature.

Study Setting

Country Selection

This project is a multicentric study. Ten institutions in seven different countries will be selected, seven of them offer residency training programs, and two fellowships only. These centers have an average of 306 residents per center and none of them adopt mindfulness programs for residents.

The participating countries will be Brazil, United States of America, Germany, Saudi Arabia, Qatar, Mexico, and Chile.

Institutions:

1. University of Illinois College of Medicine, Peoria, Illinois, United States of America
2. Tecnológico de Monterrey, Monterrey, Nuevo León, Mexico;
3. Clínica Alemana de Santiago, Santiago, Chile
4. Hospital de Clínicas de Porto Alegre, Porto Alegre, Rio Grande do Sul, Brazil
5. Instituto do Cancer do Estado de Sao Paulo (ICESP), Sao Paulo, Brazil
6. Instituto de Coração, São Paulo, Brazil
7. Universitätsklinikum Carl Gustav Carus Dresden (UKD), Germany
8. Instituto de Assistência ao Servidor Público Estadual de São Paulo, Brazil
9. King Khalid University Hospital, Riyadh, Saudi Arabia
10. Hamad Medical Corporation, Doha, Qatar

All medical institutions are tertiary hospitals. Most of the establishments are public, only a few are partially or completely privatized hospitals.

In addition, ten authors are part of the clinical body of these institutions, which makes the implementation of the study more feasible. The research should be approved by the ethics committee of each institution.

Randomization- Sequence Generation

Cluster randomization will be used with stratification taking into account geographical location, number of residents, and whether the center is public or private. Centers will be randomized to receive either the intervention or the control dummy app to reduce contamination.

Centers will be categorized as small (<100 participants) or large (>100 participants) based on the number of eligible participants per site.

To randomize a new eligible center, the clinical center will contact the randomization coordinator's office and send the center's ID number. The randomization coordinator will consult the randomization schedule using the computer system. The randomization coordinator will consider all previously randomized centers across all centers and will be provided a randomization code for that institution.

Blinding

Due to the nature of our intervention, subjective outcome, and cluster randomization, we opted to implement an open-label strategy, where only the statistician who analyses the data will be blinded. The research staff will not be blinded to the allocation.

Eligibility Criteria

Participant Inclusion Criteria:

1. Resident physicians of all specialties.
2. Meets the definition of severe burnout as measured by the MBIS (Emotional exhaustion [EE] > or equal to 27 and or Depersonalization [DP] > or equal to 10).
3. Able to read and understand English.
4. Able to provide informed consent.
5. Able to use smartphone apps and have internet access.

Participant Exclusion Criteria:

1. Not having a smartphone.
2. Previous diagnosis of a psychiatric disorder.
3. Depression or anxiety measured at T0 using the Hospital Anxiety and Depression Scale (HADS). Subjects with a score between 11 - 21 will be offered a psychiatric evaluation and support.
4. Self-reported current substance abuse (except tobacco).
5. Subjects with a history of formal mindfulness program training or current participation in one.

Recruitment Strategy

Convenience sampling will be used to recruit physicians during their residency training program. Recruitment advertisements will be automated by using flyers, personal invitations, and emails to residency training program directors and related administration personnel. Information regarding the study aims and design will be provided.

Interested residents will be scheduled for a face-to-face interview with the local research coordinator and

participants will be provided with detailed information about the study. Inclusion and exclusion criteria will be reviewed, and informed consent will be obtained prior to enrollment. Site monitors will ensure active enrollment and correct device use.

We will have a one-day run-in period before enrollment to make sure participants feel comfortable using the mobile application and with the language since most centers are in non-English native speaking countries.

Adherence

Participants will be educated about the study design and the process of randomization will be explained to them.

The study participants will be asked to use the application daily for at least 15 minutes. Application usage will be tracked by feedback user data provided by the application which the participants will be asked to send. Moreover, the participants will receive regular messages and phone calls by the research coordinator to enhance adherence. The research coordinator will call the participants weekly during the first 30 days of the study and every 10 days thereafter to motivate adherence and answer any upcoming questions. Study participants will also be informed about the importance of collecting MBIS questionnaires at 3 different points: T0, T1, and T2.

Subjects will be non-compliant if they do not use the application for at least 10 minutes for 4 consecutive days or more than 20% of the total days.

Data Management and monitoring

Data will be collected electronically in each center using REDCap, a secure web application for building and managing online surveys and databases. Data entry will be standardized in all centers and will be composed of data collected at T0, T1, and T2 as well as data provided by the Smiling Mind application on each participant's daily use measured in minutes.

Data will be stored in a confidential fashion, with no identification of individual subjects in the database. Access to the full database will be restricted to the PI and 3 collaborators responsible for the statistical analysis. Each center will be responsible for the input of its own data but will not have access to the whole database.
Access to the database will be password-protected and all electronic communication that involves data will be encrypted.

Monitoring the completion of data will be assessed independently by 3 assigned members of the research team. Data should be uploaded by each center at the previously specified time points: T0, T1, and T2.

Sample Size Calculation

Available literature regarding mindfulness-based interventions for burnout management or other similar scales measuring general well-being, perceived stress, and sleep quality in healthcare professionals have included sample sizes between 33 and 131 participants (Spinelli et al, 2019).

We considered an inter-cluster correlation coefficient of 0.01, an alpha level of 0.05, a power level of 80%. Using previous studies considering a mean difference of 7 in the emotional exhaustion component of the MBIS (Goodman, M. J., & Schorling, J. B., 2012; Krasner, M. S., Epstein, R. M., Beckman, H., Suchman, A. L., Chapman, B., Mooney, C. J., & Quill, T. E., 2009), a standard deviation of 11.46 (Bronson, K., 2017; Gómez-Gascón, T., Martín-Fernández, J., Gálvez-Herrer, M., Tapias-Merino, E., Beamud-Lagos, M., Mingote-Adán, J. C., & EDESPROAP-Madrid, G., 2013), an average of 305 participants in each group is calculated. Considering a 25% drop out rate we would need a total of 400 participants per arm, or a total of 800 participants to detect a difference in effect. An overall target of 80 participants should be recruited per center.

Statistical Analysis for primary and secondary outcomes

We will compare participants allocated to the Smiling Mind app MBI with those to the dummy app analyzing the data according to the intention-to-treat principle. All analyses will be adjusted for clustering within sites and geographical location.

The primary outcome of the emotional exhaustion aspect of the MBIS at 30 days will be analyzed by a linear mixed regression model (general estimating equation) to correct for standard error in the cluster data. The secondary outcomes of depersonalization and reduced personal accomplishment aspects of the MBIS at 30 days and the change in all three aspects of the MBIS at 60 days will be analyzed similarly. Sociodemographic data, adherence, and MBIS scores will be compared using Chi2 or Fisher's test, and T-Test or Wilcoxon log-rank test, accordingly.

The effect of the intervention over time at T0, T1, and T2 within the intervention group and for the control group will be analyzed separately. For that, we will also use linear regression mixed models to evaluate whether

the effects of the intervention were maintained at 60-day follow-up.

All statistical analyses will be made with Stata/IC 16.1.

Missing Data

A sensitivity analysis adjusting for all centers based on per protocol analysis will be done to estimate the impact of the missing data on the results. This analysis will be done by comparing the results with and without adjusting for centers. The missing data will be estimated through the multiple imputation method, which will be done by using the MBIS on a linear regression.

DISCUSSION

Burnout is a major issue among physicians negatively affecting their quality of life and the medical care they provide (West et al., 2016). Mindfulness exercises provided through mobile apps are an attractive alternative to MBSR programs to reduce resident physicians' burnout, (Wen et al., 2017) but have not been widely studied.

In this study, we propose a unique phase-II multicenter, open-label with statistician blinded, cluster randomized, controlled trial to evaluate the effect of mobile app-based mindfulness practice (Smiling Mind) on reducing the burnout levels of residents from different specialties. The Smiling Mind application contains a wide variety of high-quality meditation programs that are free, easy to use, and downloadable for offline use.

The study targets resident physicians who have been found to be particularly vulnerable to burnout and were underinvestigated in the past (Low et al., 2019). Achieving resilience through mindfulness practice will leave a healthy and durable physician workforce for the future.

We opted to use cluster randomization to account for the high possibility of contamination among residents working in one hospital when using either Smiling Mind or the dummy application. This decision significantly impacted our sample size calculation and resulted in a total of 400 residents in each arm. A large sample size along with the inclusion of residents of multiple specialties in multiple centers will give us insight about the prevalence of burnout among resident physicians and would allow performing further sub-group analysis to highlight the important risk factors associated with burnout.

For the primary outcome, we used the emotional exhaustion aspect of the MBIS to measure burnout. It was thought that using the three components of the MBIS would triple the type I error of the study. To keep an overall alpha of 0.05 would require a further increase in the sample size which is not feasible.

In contrast to previous studies, we decided to use a control dummy mobile application with simple educational contents about burnout to mitigate the placebo effect.

Limitations

Our study protocol has a few limitations. The large sample size will have implications on the recruitment process. We addressed this by recruiting 10 centers located in North America, South America, Europe, and Asia to facilitate the recruitment process.

Furthermore, the study is an open-label to the participants and physicians which might bias the assessment of the outcome as measured by the MBIS. Poor compliance is anticipated from previous studies and this will be addressed by close follow up of the participants. Participants will also be asked to send the feedback user data provided by the application.

We believe that even if our trial gets negative results, we will gather relevant epidemiology information on the current physician's burnout level at a worldwide scale that will be useful for other investigators and practitioners. Currently, we are living in the COVID-19 pandemic that is affecting healthcare professionals around the world, where how to cope with job stress and build resilience has become more relevant than ever. In addition, this trial will help us identify if mindfulness is ineffective. In this case, alternative approaches will have to be proposed in future clinical studies to manage this problem that impacts negatively on healthcare professionals.

CONCLUSION

Our proposed research has the potential to determine the effectiveness of an easily accessible mobile-based mindfulness intervention on resident physician burnout. If this study demonstrates that the Smiling Mind app reduces resident physicians' burnout, this can be applied in residency programs worldwide to improve residents' quality of life and enrich medical care with a resilient workforce.

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Conflict of Interest

The authors declare no conflict of interest.

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APPENDIX

Maslach Burnout Inventory (MBI)

The inventory consist of 22 questions which have five graded Likert-type answers. To determine the risk of burnout, the MBI explores three sub-scales: emotional exhaustion, depersonalization and personal accomplishment. A high score in the first and third sections and a low score in the second section may indicate burnout.

Questions	Never	Rarely	Sometimes	Frequently	Always
I. Emotional Exhaustion					
I feel emotionally drained from my work	0	1	2	3	4
I feel used up at the end of the workday	0	1	2	3	4
I feel fatigued when I get up in the morning and have to face another day on the job	0	1	2	3	4
Working with people all day is really a strain for me	0	1	2	3	4
I feel burned out from my work	0	1	2	3	4
I feel frustrated by my job	0	1	2	3	4
I feel I'm working too hard on my job	0	1	2	3	4
Working with people directly puts too much stress on me	0	1	2	3	4
I feel like I'm at the end of my rope	0	1	2	3	4
II. Personal Accomplishment					
I can easily understand how my recipients feel about things	0	1	2	3	4
I deal very effectively with the problems of my recipients	0	1	2	3	4
I feel I'm positively influencing other people's lives through my work	0	1	2	3	4
I feel very energetic	0	1	2	3	4
I can easily create a relaxed atmosphere with my recipients	0	1	2	3	4
I feel exhiliarated after working closely with my recipients	0	1	2	3	4
I have accomplished many worthwhile things in this job	0	1	2	3	4
In my work, I deal with emotional problems very calmly	0	1	2	3	4
III. Depersonalization					
I feel I treat some recipients as if they were impoersonal 'objects'	0	1	2	3	4
I've become more callous toward people since I took this job	0	1	2	3	4
I worry that this job is hardening me emotionally	0	1	2	3	4
I don't really care what happens to some recipients	0	1	2	3	4
I feel recipients blame me for some of their problems	0	1	2	3	4

Image 1: Maslach Burnout Inventory (Maslach et al, 1996)

Hospital Anxiety and Depression Scale (HADS)

Tick the box beside the reply that is closest to how you have been feeling in the past week. Don't take too long over your replies: the immediate reply is the best one.

D	A		D	A	
		I feel tense or 'wound up':			**I feel as if I am slowed down:**
	3	Most of the time	3		Nearly all the time
	2	A lot of the time	2		Very often
	1	From time to time, occasionally	1		Sometimes
	0	Not at all	0		Not at all
		I still enjoy the things I used to enjoy:			**I get a sort of frightened feeling like 'butterflies' in the stomach:**
0		Definitely as much		0	Not at all
1		Not quite so much		1	Occasionally
2		Only a little		2	Quite often
3		Hardly at all		3	Very often
		I get a sort of frightened feeling as if something awful is about to happen:			**I have lost interest in my appearance:**
	3	Very definitely and quite badly	3		Definitely
	2	Yes, but not too badly	2		I don't take as much care as I should
	1	A little, but it doesn't worry me	1		I may not take quite as much care
	0	Not at all	0		I take just as much care as ever
		I can laugh and see the funny side of things:			**I feel restless as I have to be on the move:**
0		As much as I always could		3	Very much indeed
1		Not quite so much now		2	Quite a lot
2		Definitely not so much now		1	Not very much
3		Not at all		0	Not at all
		Worrying thoughts go through my mind:			**I look forward with enjoyment to things:**
	3	A great deal of the time	0		As much as I ever did
	2	A lot of the time	1		Rather less than I used to
	1	From time to time, but not too often	2		Definitely less than I used to
	0	Only occasionally	3		Hardly at all
		I feel cheerful:			**I get sudden feelings of panic:**
3		Not at all		3	Very often indeed
2		Not often		2	Quite often
1		Sometimes		1	Not very often
0		Most of the time		0	Not at all
		I can sit at ease and feel relaxed:			**I can enjoy a good book or radio or TV program:**
	0	Definitely	0		Often
	1	Usually	1		Sometimes
	2	Not often	2		Not often
	3	Not at all	3		Very seldom

Please check you have answered all the questions

Scoring:
Total score: Depression (D)_____ Anxiety (A)_____
0-7 = Normal
8-10 = Borderline abnormal (borderline case)
11-21 = Abnormal (case)

Image 2: Hospital Anxiety and Depression Scale (HADS questionnaire)