Research Module Assignment 2: A research proposal for an MSc or MA thesis in mindfulness- based approaches. June 2011.
Word Count: 2,455 (excluding appendices)

Title of Project

Effects of a novel, interactive, internet delivered intervention on mindfulness in a healthy population.

The potential value of addressing this issue

Mindfulness-based interventions typically take the form of a complex eight week, instructor lead, group courses. The proposed study tests the viability of an on-line component that could either form part of an entirely on-line intervention or supplement a conventionally delivered course. If interventions using this kind of approach were found to be efficacious they would be of value because they are highly scalable, cheap and accessible to patients who can't or don't want to attend group therapy sessions. They would also provide feedback on adherence to mindfulness programs.

Background to the study

Mindfulness is a component of contemplative religious traditions (particularly Buddhism) that involves paying reflective, non-judgemental, kindly awareness to ones current experience (Shapiro, Carlson, Astin, & Freedman, 2006).

Since the 1980's there has been an expansion in the use of mindfulness meditation practices in clinical settings for a range of disorders including depression (Segal, Williams, & Teasdale, 2002), substance abuse (Bowen et al., 2006), eating disorders (Tapper et al., 2009), chronic pain (Schmidt et al., 2011) and quality of life issues (Carmody & Ruth A Baer, 2008).

Kabat-Zinn (1996) established the use of mindfulness as an intervention with the eight week Mindfulness Based Stress Reduction (MBSR) course. This approach was broadly taken up by Segal et al. (2002) in the 8 week Mindfulness Based Cognitive Therapy (MBCT) course. Many studies have been carried out that are based on variations of these two forms of intervention.

From the point of view of research there are a number of difficulties in measuring the

efficacy of these interventions.

- The courses are complex with a large number of components.
- Courses involve a long contact time with trainers who may influence results.
- Daily home practice is seen as a vital component of the interventions but is difficult to measure and is seldom recorded during trials although it has been shown to be positively correlated with beneficial outcomes (Huppert & Johnson, 2010).

There are also hurdles to widespread deployment of approaches based on MBSR/MBCT. Courses are resource limited and require local trainers to be on hand to meet demand. Courses may not be available when most needed by patients. Not all patients are prepared to take part in group sessions. The eight week interventions were designed for seriously ill people and may not be appropriate for earlier interventions.

There have been attempts to deliver interventions over the internet but these have tended to be an automation of the standard MBCT/MBSR type course with the instructors appearing on video. They do not take full advantage of the web as a mechanism for delivering interactive applications rather than just content (e.g. Ljótsson et al., 2010)

Internet technology, especially that termed Web 2.0, allows for the delivery of interactive applications through the medium of web browsers and via mobile devices such as smart phones and tablets. This has potential for providing tools that help people engage with, and build, a mindfulness practice that is beneficial for their well-being.

A key technique used in mindfulness practice in many religious traditions and as part of MBSR/MBCT is “Mindfulness of Breathing”. This involves paying close attention to the breath as a key to gaining equanimity about ones broader experience – rather than being engaged with the narrative thought stream. The intervention proposed here is designed to help participants engage with their breath-cycle by interacting with an application.

The hypotheses and aims

– Hypothesis

Using a purely computer based mindfulness training exercise for ten minutes each day over a period of two weeks can positively affect measures of general well-being and mindfulness.

– Secondary Aim

This is a novel intervention and requires commitment from the participant over the course of two weeks. A secondary aim is therefore to examine the retention rate and the level of adherence.

Participants: recruitment methods, age, gender, exclusion/inclusion criteria

The study will target healthy adult participants who are familiar with the use of computers. People will be asked not to take part if they have an current mental health problem or chronic breathing difficulties.

Participants will be recruited using the advertisement text shown in **Appendix B**. These advertisements will initially be sent to Bangor University mailing lists. The webapp will be monitored and if it is performing correctly the same advertisement will be sent to a broad range of UK mailing lists with a general interest in health. A press release will be distributed and the study will be promoted through social media. The aim will be to get as larger a number of participants from as broader range of backgrounds as possible.

Research design

The proposed study is a two arm, randomised, controlled longitudinal study. Randomisation is between a mindfulness of breathing exercise and an active control that involves solving anagrams. Details are given in the following section.

The study would run on a rolling basis with participants joining in response to an advertisement at any point over a six month period.

Procedures to be employed

The intervention will be entirely web based. A web based application (webapp) will be built and hosted on a web server. Recruitment and support of participants will also be web based apart from the supply of emergency contact details.

– From the participant's perspective

The diagram in **Figure 1** illustrates interactions with participants. Potential participants will be attracted via the advertisement (see text in **Appendix B**). They will visit the home

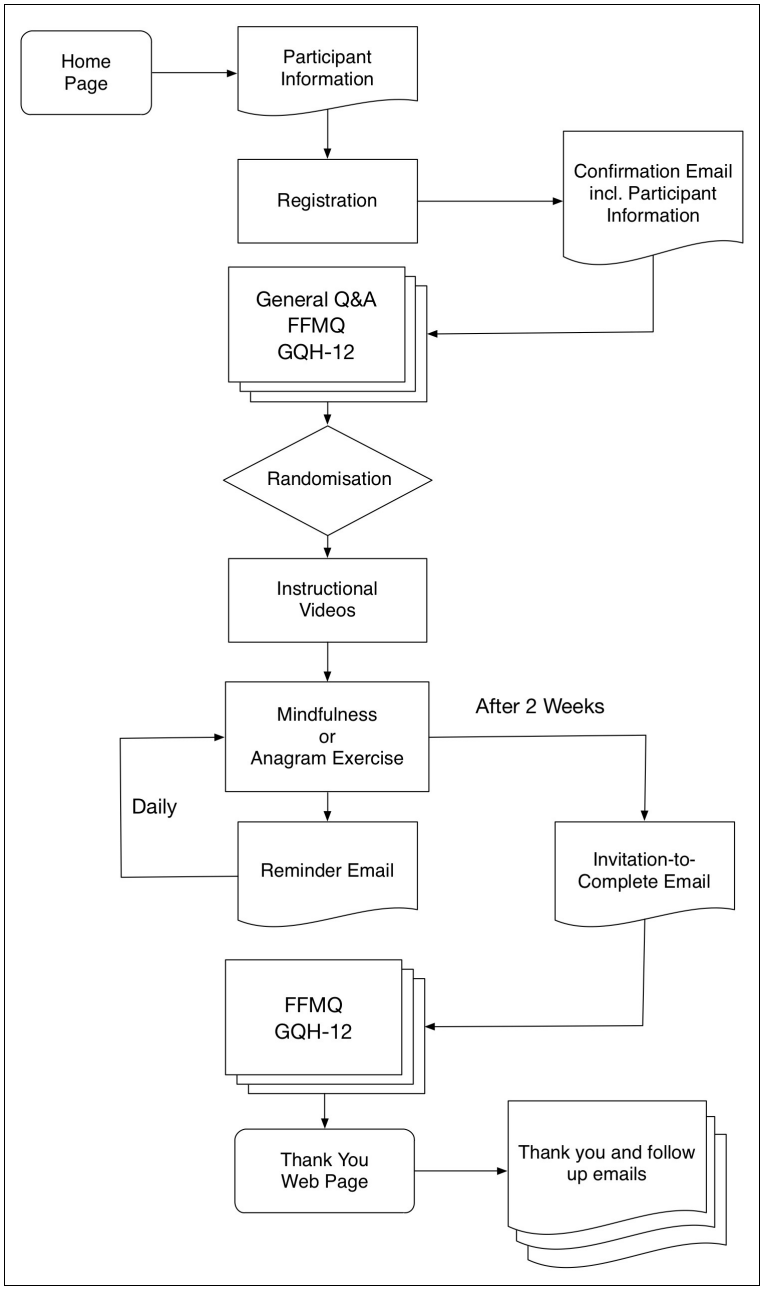

Figure 1: Interactions between participant and webapp.

page of the website which will repeat the advertisement text and have a button entitled "Learn More". Clicking this button will lead on to a page with the full participant information (**Appendix A**). At the bottom of this page will be two radio buttons giving a choice between the statements:

1. "I understand the information given and agree to participate. (A copy of the information above will be emailed to you)." .
2. "I do not want to participate in the study".

The default will be set to option two. There will be two buttons:

1. “Continue”
2. “Cancel”

To join the study the participant has to check option 1 and click button 1. Clicking button 1 with option 2 selected will give a warning message. Clicking button two will display a thank you message and redirect to the home page.

If the participant chooses to join the study they are given a registration page where they provide their name and a valid email address. A confirmation email will be sent to that address containing a personalised link back to the webapp along with a copy of the participant information. They must click on the link in the email to confirm their email address. This link will initially take them to the pre-intervention questionnaires. Once they have completed the questionnaires they will be randomly assigned to either the mindfulness exercise or the anagram exercise. They will watch an appropriate five minute video that describes how to complete the task. This video will be available for them to watch again at any time. They will then do either a mindfulness exercise or an anagram exercise (depending which arm they have been assigned to).

Figure 2: Screen displayed during stage one of the Mindfulness Exercise.

Each day participants will receive an email reminding them to carry out their ten minute

exercise. The email will contain their personal link to the webapp so the participant will not have to log in every time. These emails will continue for two weeks unless the participant fails to carry out an exercise on four consecutive days in which case it will be assumed they no longer wish to adhere to the programme and the emails will stop. Emails will resume should the participant return to carry out an exercise.

After two weeks the participant will be sent an email inviting them to complete the GHQ-12 and FFMQ questionnaires again even if they have already stopped doing the daily exercises. On completion of the questionnaires they will see a thank you page informing them that their active part in the study is complete but, as a courtesy, they are free to come back to the site using their personalised link at any time and either do the mindfulness exercise or the anagrams.

– Participant Identifiers

When the participant registers they are issued with a personalised link back to the webapp containing a random string of characters. This link remains constant and will always take them to the appropriate part of the study. They will be asked not to share the link with anyone else. There is a danger that they could share the link but it is judged the benefits of participants not having to provide login credentials on each visit outweigh the associated risks. Should the link fall into the wrong hands it would provide no access to personal information about the participant as it only provides the ability to add data.

– Mindfulness Exercise (treatment)

Participants will watch a five minute video explaining how to carry out the exercise. To start the exercise they must work through a five point checklist:

1. I have watched the guidance video. (You don't have to watch it before every session.)
2. I am not likely to be disturbed in the next 10 minutes.
3. I have turned off any TV/Radio/Music.
4. I am sitting in an erect, dignified, comfortable position.
5. I'll go at my own pace and click 'Stop' if I get into difficulties.

When they have checked these points a window appears and a bell sounds (**Figure 2**). For the next four minutes the participant focuses on their breath and clicks on the screen at the

end of each out-breath. A bell sounds and the participant then spends four minutes clicking on the screen prior to each in-breath. A bell sounds and the participant spend two minutes only focusing on their breath and clicking the screen if they become distracted. After this they are presented with a form that contains four sliders and a text box (**Figure 3**).

A working prototype of the treatment and the guidance video are available here: http://breathfollower.appspot.com/. The text of the guidance video is included in **Appendix C**.

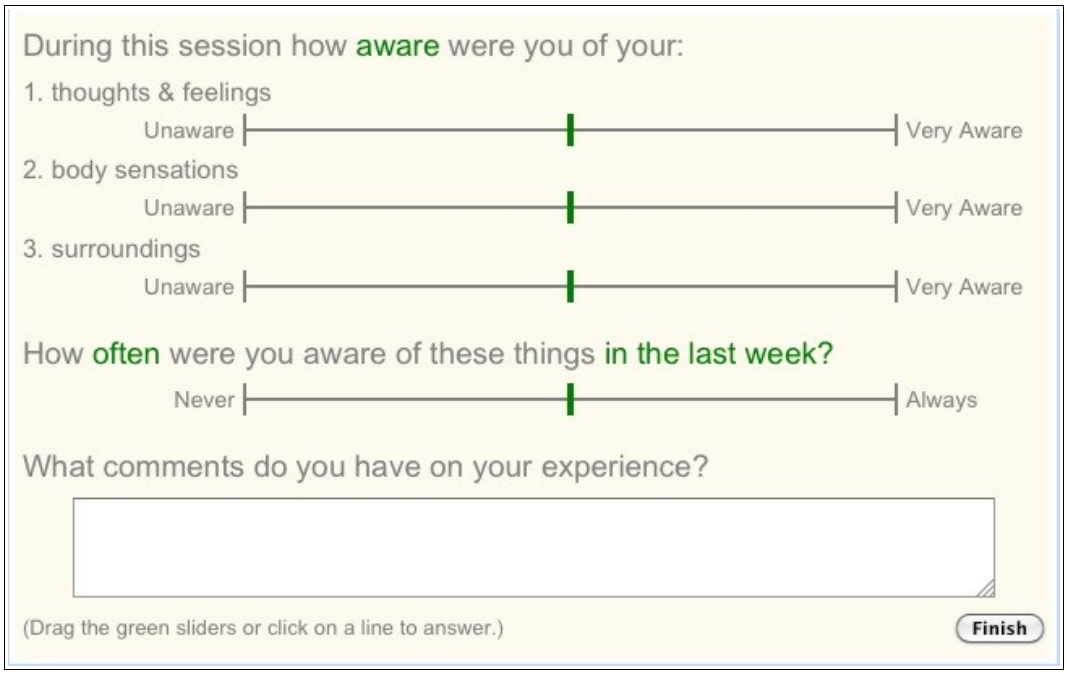

Figure 3: Screen displayed at the end of the Mindfulness Exercise.

– Anagram Exercise (control)

The anagram exercise will be as similar as possible to the mindfulness exercise in terms of look and feel. The same checklist of questions will result in a window of the same size appearing but, instead of following their breath participants will be presented with a simple word puzzle. The top half of the window will contain six to nine letters in a random order. The bottom part of the window will contain a list of words, one of which is made up of the randomly arranged letters. The participant clicks on this word to score a hit. Clicking on the wrong word scores a miss. The window is then refreshed with a new set of letters and words. At first their will only be two candidate words in the list but each time the

participant scores a hit the number of candidate words increases – thus increasing the difficulty of the task. The hit and miss scores are displayed in the top left of the window and a count down timer is displayed in the top right of the window.

Measures to be employed

An initial questionnaire will include six questions to characterise the population and help control for participants with previous experience of meditation (see **Appendix D**).

The General Health Questionnaire 12 (GHQ-12) (Goldberg, D. & Williams, P., 1988) will be used pre and post intervention to characterise the health of participants and assess any improvements.

The Five Facets of Mindfulness Questionnaire (FFMQ) (R. A Baer, Smith, Hopkins, Krietemeyer, & Toney, 2006) will be used pre and post intervention to measure changes in mindfulness in the five different facets. This questionnaire consists of 64 questions scored on a 5-point Likert-type scale (1 = never or very rarely true, 5 = very often or always true). Example questions are:

- I criticize myself for having irrational or inappropriate emotions.
- I'm good at finding the words to describe my feelings.
- I find myself doing things without paying attention.

Data analysis

The main hypothesis will be tested by looking for significant differences between control and treatment arms on the five facets of the FFMQ and the GHQ-12. P-values and effect sizes will be calculated. Subsequent analyses will compare drop out and adherence rates between treatment and control and a exploratory factor analysis will be used to see if there are any correlations between treatment, control, adherence, retention, pre-treatment scores and post-treatment scores.

Potential offence/distress to participants and how it would be managed

It is unlikely the study will cause offence or distress. Only healthy individuals will be invited to take part and they will be encouraged to consult a professional should they express any doubts. During exercises a 'Stop' button will always be visible. Participants will

be sent a limited number of emails and these will stop if they fail to respond to.

Procedures to ensure confidentiality and data protection

Data will be stored within the webapp on a password protected server hosted in a secure data centre. Data will be backed up to an encrypted file stored on a password protected personal computer. Identifying data (name, email and the personalised link) will be stored within its own table within the database. For analysis a copy of the database will be taken and the identifying data deleted – leaving only anonymised data for analysis. Analysis will be carried out on the same password protected personal computer. On publication of results the data on the server and encrypted backups will be destroyed.

How consent is to be obtained

Participants will give consent by following the procedure outlined above – see 'From the participant's perspective'. The text of the participant information and consent page is given in **Appendix A**.

Information for participants

This information is provided in **Appendix A** and **Appendix B**.

Approval of relevant professionals

This is not foreseen to be necessary. If a participant expresses any problems during study they will be directed to their GP.

Feedback to participants

When the data gathering phase of the study is complete a summary email will be sent this will include a reminder that the server remains available. When the analysis of the data is complete and the server is going to be taken down a summary of the results will be emailed along with a date for shutdown of the server.

References

Baer, R. A, Smith, G. T., Hopkins, J., Krietemeyer, J., & Toney, L. (2006). Using self-report assessment methods to explore facets of mindfulness. *Assessment*, *13*(1), 27–45.

Bowen, S., Witkiewitz, K., Dillworth, T. M., Chawla, N., Simpson, T. L., Ostafin, B. D., Larimer,

M. E., et al. (2006). Mindfulness Meditation and Substance Use in an Incarcerated Population. *Psychology of Addictive Behaviors*, *20*(3), 343-347. doi:37/0893-164X.20.3.343

Carmody, J., & Baer, Ruth A. (2008). Relationships between mindfulness practice and levels of mindfulness, medical and psychological symptoms and well-being in a mindfulness-based stress reduction program. *Journal of Behavioural Medicine*, *31*(1), 23-33. doi:10.1007/s10865-007-9130-7

Goldberg, D., & Williams, P. (1988). *A users guide to the General Health Questionnaire.* Slough: NFER-Nelson.

Huppert, F. A., & Johnson, D. M. (2010). A controlled trial of mindfulness training in schools: The importance of practice for an impact on well-being. *The Journal of Positive Psychology: Dedicated to furthering research and promoting good practice*, *5*(4), 264. doi:10.1080/17439761003794148

Kabat-Zinn, J. (1996). *Full Catastrophe Living: How to Cope with Stress, Pain and Illness Using Mindfulness Meditation*. London: Piatkus Books.

Ljótsson, B., Falk, L., Vesterlund, A. W., Hedman, E., Lindfors, P., Rück, C., Hursti, T., et al. (2010). Internet-delivered exposure and mindfulness based therapy for irritable bowel syndrome--a randomized controlled trial. *Behaviour Research and Therapy*, *48*(6), 531-539. doi:10.1016/j.brat.2010.03.003

Schmidt, S., Grossman, P., Schwarzer, B., Jena, S., Naumann, J., & Walach, H. (2011). Treating fibromyalgia with mindfulness-based stress reduction: Results from a 3-armed randomized controlled trial. *PAIN*, *152*(2), 361-369. doi:16/j.pain.2010.10.043

Segal, Z. V., Williams, J. M. G., & Teasdale, J. D. (2002). *Mindfulness-based Cognitive Therapy for Depression: A New Approach to Preventing Relapse* (1st ed.). Guilford Press.

Shapiro, S. L., Carlson, L. E., Astin, J. A., & Freedman, B. (2006). Mechanisms of mindfulness. *Journal of Clinical Psychology*, *62*(3), 373-386.

Tapper, K., Shaw, C., Ilsley, J., Hill, A. J., Bond, F. W., & Moore, L. (2009). Exploratory randomised controlled trial of a mindfulness-based weight loss intervention for women. *Appetite*, *52*(2), 396-404. doi:16/j.appet.2008.11.012

Appendix A: Participant Information And Consent

[**N.B.** Some of the contact information is not know at this stage]

Project Title

Effects of a novel, interactive, internet delivered intervention on mindfulness in a healthy population.

Investigators

Roger Hyam – Principle Investigator, Bangor University.

Prof. A. N. Supervisor – Bangor University

Dr Another Supervisor – Another University

Nature of the Research Project

This is a research project to find out if doing a ten minute, daily, on-line exercise can improve well-being in healthy people. Specifically we are interested in seeing if levels of mindfulness can be changed. Mindfulness is a state of mind that has been shown to correlate with high levels of mental well-being.

If the exercises work in healthy volunteers then we may be able to develop new treatments based on this approach. This is early research so we don't expect it to lead directly to new treatments.

To take part in the study you should be:

- Over 16 years of age.
- In good health.
- Not suffering from a chronic respiratory disorder.
- Have daily broadband access to the internet in a quiet location where you won't be disturbed.
- A valid email address you will check daily for the two weeks of the study.

Procedures of the study

If you choose to take part in the study you will need to spend around twenty minutes answering a set of questions on-line (tick boxes), then ten minutes, undisturbed each day to do an on-line exercise. After two weeks you will need another twenty minutes to answer a second set of questions on-line (more tick boxes). This will conclude your participation in the study.

For your two weeks of participation you will be randomly assigned one of two possible exercises. We will compare results between people who did different exercises. At the end of your two weeks you will be given access to do both the exercises should you wish. You will be able to see what the other exercise was and, if you like, carry on doing the exercise till the whole study is complete (around six months to a year). Anything you do after the first two weeks will not count as part of the study and is just for fun.

Which exercise you do will be chosen randomly by the computer. You will do the same exercise each day for your two weeks. You won't know what the other exercise is until the

two weeks are up.

The study will be conducted entirely in English.

Benefits and harms of procedures

The questionnaires and the exercises are simple and unlikely to cause you any harm.

You may benefit from slightly increased levels of mindfulness and concentration.

Other than your time and internet access you should incur no costs in taking part in the study. Unfortunately we are unable to make any payment for your participation or refund any costs incurred.

Confidentiality

We will store your name and email address for the duration of the study. It will only be used to contact you in connection with the study and will not be passed to any third party. It will be kept separate from any data about the exercises you do. We will destroy it at the end of the study.

Results

When we have analysed the data from the whole study we will send you a summary of our findings. Unfortunately we will be unable to provided details of your individual results.

More Information

If you would like to know more, either before you start or during the course of the study, then you can contact Roger Hyam, the principle investigator, by email on roger@hyam.net, by phone on *** **** or my post *** *****.

Complaints

In the case of any complaints concerning the conduct of research, these should be addressed to Professor Oliver Turnbull, Head of School of Psychology, Bangor University, Gwynedd, LL57 2DG.

Consent

Participation in the study is entirely voluntary, and you are free to refuse to take part or withdraw at any time without penalty. To withdraw from the study after you have started simply ignore any emails you receive. We will send you a maximum of four.

Appendix B: Wording for Advertisements

[**N.B.** Some of the contact information is not know at this stage]

- Very Short Advert for Twitter and Other Social Media

An on-line study is looking at effects of regular mindfulness exercises. Please consider taking part here: http://www.*****

- Full Advertisement

Can a web application improve mental well-being?

We are looking for normal, healthy people, over the age of sixteen who have daily access to the internet to take part in a two week study. The study hopes to show that doing a on-line exercise for ten minutes each day can have a significant, positive effect on levels of mindfulness and mental health.

If you are interested in volunteering to participate please visit our website http://www.****

Roger Hyam, Principle Investigator, Bangor University...

Appendix C: Script for Mindfulness Exercise Guidance Video

[**N.B.** This script uses the term 'Breath Follower' which is the working name for the prototype application]

A Breath Follower session lasts ten minutes and involves clicking on the screen at certain points during your breath-cycle.

Most importantly you do not attempt to alter the natural flow of breath – you just observe it.

At the end you answer some simple reflective questions.

By anchoring your attention on your breath and holding it there you will find that you become more aware not only of your breath but also of other aspects of your current experience.

Your focus should be entirely on your own experience. What are your bodily sensations? What are your thought patterns?

You are not trying to "do" anything with the computer – apart from report your experience.

Before you start make sure you have turned off all music, TV, and radio. This is important because your mind will latch on to any narrative or melody and follow that – rather than tuning into your current experience.

Sit in an upright but not stiff position.

Try sitting forward on your seat – so your back is not supported.

Rest your arms on the table. Perhaps with the mouse in front of you – rather than to one side.

If, at any point, you feel it is becoming too much – just stop.

Don't push yourself beyond what feels safe.

Sessions are divided into three stages.

During stage one you click on the flower, after, each, out, breath.

Remember that you are only following your breath, as it is, without trying to alter it.

Take your attention to your breath and wait until the end of an out breath comes around.

Just when you think you have finished breathing out – click the flower.

Watch as your breath flows in and out and, just as you finish breathing out again, click the flower.

As you continue following your breath and clicking the flower, you may become distracted and forget to click. It doesn't matter. Just wait till the end of the next out breath and click the flower then.

If you are finding it difficult, try placing your spare hand on your belly so that you can feel it moving as you breathe.

Stage two is similar to stage one but you click the flower at a different point in your breath-cycle.

You click the flower just before you breathe in.

If you become distracted and forget to click, don't worry. Just wait till a breath is about to come again and click then.

You don't have to keep your eyes open. If you find it more comfortable you can half close or shut them completely.

In stage three you just follow your breath without clicking on each cycle.

If you find you have drifted off and have stopped watching your breath, just acknowledge this, by clicking the flower once, and bringing your attention back to the breath.

You can pause on this screen as long as you like.

When you are ready, click the button.

Reflect on the questions then slide the green bars to the appropriate points between “unaware” and “very aware”, “Never” and “Always”.

If you like, you can click on the right spot on the grey bar and the green slider will jump straight there.

Reflecting on your experience is an important part of the learning process. It feeds into the next time you use the application and also your daily experience, so don't skip it.

Ideally, BreathFollower, should be used regularly as the effects are cumulative.

Please watch this video again if you feel you need to.

Contact Roger with any questions.

Good luck!

Appendix D: Initial Demographic Questionnaire

Six questions. Five have drop down choice boxes.

- Age in Years:
    - Choice of 16 to 100
- Sex:
    - Male
    - Female
- Highest Formal Education:
    - School
    - Vocational Qualification
    - University Degree
    - University Higher Degree
    - Rather not say
- First Part of Your Postcode:
    - Restricted to two letters followed by one or two digits.
- Do you regularly engage in some form of contemplative practice:
    - No
    - Chanting
    - Meditation
    - Prayer
    - Tai Chi
    - Yoga
    - Other
- For how many years have you been carrying out this practice?
    - No practice
    - Less than 2 years
    - 3-5 years
    - 6-10 years
    - 10+ years