WIND FARMS
AND HEALTH

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Title: **Assessing the health effects of one month of simulated wind farm infrasound: A community-based randomised controlled trial**

Short title: **Community-based study of health effects of infrasound**

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This study will be performed in the homes of participants living in Sydney.

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1. Introduction

Background and rationale

The drive to develop renewable energies to reduce fossil fuel consumption has resulted in increasing efforts to harvest wind power as a method of renewable energy delivery. This has resulted in the construction of multiple wind turbine clusters or "wind farms" in rural areas in Australia to generate power.

Health concerns

Implementation of wind power programs has been opposed by a number of communities, in part due to claims that wind farms pose a risk to health. Concerns have largely focused on audible or non-audible noise, such as infrasound, alleged to cause a range of negative effects on sleep, vestibular function and mood. Some people have referred to this constellation of symptoms as wind turbine syndrome (WTS).

Wind Turbine Syndrome (WTS)

WTS refers to a cluster of symptoms reported in case studies by Pierpont.(1) In that series individuals reported sleep disturbance, headache, tinnitus (ringing in the ears), a sensation of pressure in the ears, dizziness, vertigo, nausea, visual blurring, palpitations, irritability, problems with concentration and memory and panic episodes associated with sensations of internal pulsation or quivering when awake or asleep.(1) In that report, the symptoms typically improved during holidays or other withdrawal from the wind turbine environment and returned with re-exposure. There are case reports of WTS being present in one family member but not in another who lives in the same dwelling.(2) It has been proposed that people who are particularly 'sensitive' to noise may be at greatest risk. It has been argued that WTS is caused by infrasound generated by wind turbines.(1, 3, 4)

Alternative Explanations

Some experts have discounted the association between the symptoms of WTS and exposure to noise from wind turbines. They suggest the symptoms are the result of a nocebo effect, in which a patient can be convinced that something benign is making them sick. It is argued that the annoyance and health effects some people experience when unwanted turbines are erected in their local areas are more strongly related to subjective factors such as the visual impact of the turbines, attitudes towards wind energy and whether there is economic benefit from turbines, rather than to noise itself, both audible and inaudible (i.e. infrasound).(4, 5) This level of annoyance may be the primary mediating agent causing sleep disturbance and increased psychological distress.(6) Stress is considered another mechanism by which noise can impact on human health.(7) Where stress effects are present, they may be dependent on the level of annoyance induced by the noise.(8)

Noise from wind turbines

Wind turbine noise comprises the following range of spectra of relevance to this study:
i. Infrasound (frequencies less than 20 Hz),
ii. Low Frequency (LF) sound (frequencies 20-200 Hz)
iii. High Frequency (HF) sound (frequencies above 200 Hz).

Whilst infrasound is regarded as being below the audible range, if its level is high enough it can be "sensed". This sensation is best described as a sensation of pressure on the ears(9) or a sensation or sound of deep humming/rumbling.(2) There is no sense of pitch attributable to infrasound. In contrast, noise in both the LF and HF range is usually audible with a sense of pitch.

Wind turbine noise encompasses the whole of the sub-audible and audible frequency spectrum – infrasound, LF sound and HF sound including amplitude modulation ("swish") effects of the higher frequency sounds. It is not known which of those components contribute to annoyance and which contribute to the alleged health effects.

Infrasound

The nature of infrasound is now well understood(10) based on acoustical studies performed at Bluff Wind Farm (SA), Cape Bridgewater Wind Farm (VIC) and Shirley Wind Farm (USA).(11) The sound is comprised of the blade pass frequency (typically 0.7-0.8Hz) and its harmonics. The maximum sound pressure level at these frequencies was 89.5dB Lin Peak (recorded at Shirley Wind farm).

Community concerns are focused on infrasound

The main community group advocating that wind farms have deleterious effects on health is the Waubra Foundation. The foundation's chair, Mr Peter Mitchell recently served as an observer on the NHMRC Wind Farms Health Effects Reference Group. The foundation recently published a statement "Acoustic Engineering Investigation into Airborne and Ground-Borne Pressure Pulses from Wind Turbines at Cape Bridgewater"(12) (Mr Peter Mitchell, personal communication to Prof Grunstein) which summarises their concerns. It states that although infrasound is only audible at very high levels, "it can be damaging to the human body at levels well below audibility". Moreover the document states that "Infrasound has long been known to be dangerous and harmful to humans, especially with chronic exposure. Infrasound persists for much greater distances than audible sound and, unlike audible sound, penetrates virtually all building structures (including double glazing) with ease; and often increases the impact by resonating with internal structures in the house". While infrasound is ubiquitous, anti-wind farm community groups state that wind turbines have a specific infrasound signature or profile that differs from common sources of infrasound such as ordinary wind, household appliances or waves on a beach. This profile is "a necessary tool for investigating noise from wind turbines anywhere".

In addition, the foundation recommended that research also measure subjective "sensation" of vibration related to infrasound by use of specific self-report scales, investigation be undertaken inside houses and continue over sufficient periods of time, such

as 6 weeks. It is the infrasound component of the noise that is claimed by those suffering nausea, dizziness and other symptoms that is the primary cause of their symptoms.

Given these views from community groups and the lack of high quality research on health effects identified by the NHMRC Reference Group,(13) we propose that the correct approach to addressing the issue of wind farm noise and health effects is to focus on robustly assessing the effects of infrasound using a synthesised sound that matches the infrasound profile of wind farms in a randomised controlled trial of exposure.

Possible biological mechanism for vestibular effects

The following observations indicate that infrasound may be capable of producing audio vestibular disturbances, particularly in susceptible individuals.

1) At very low frequencies, the cochlear outer hair cells (innervated by type II afferents which do not participate in conscious hearing) are stimulated by sounds below the audible range.(14)

2) Structures involved in endolymph volume regulation are influenced by infrasound. In experimental animals, brief (1-2 min) exposures in the moderate to intense ranges of low frequency tones have induced endolymphatic hydrops.(15)

3) Humans, monkeys and guinea-pigs do not show evidence of vestibular activation by high levels of infrasound(16) but some inner ear pathologies lower the thresholds for vestibular activation due to the presence of an additional low resistance pathway or “third window”: superior semicircular canal dehiscence, large vestibular aqueduct syndrome.(17, 18) Further, endolymphatic hydrops and vestibular migraine, which are characterized by sound hypersensitivity, may also provide additional biologically plausible pathways by which infrasound may have health effects. Hence, there is a biologically plausible mechanism for the physiological effects of infrasound. However, as yet there is no evidence that these effects actually occur. The study proposed here is designed to provide data in this area.

Noise sensitivity and annoyance

Noise sensitivity and annoyance are considered to be related but not identical concepts.(19) Noise sensitivity is a distinct psychological trait and refers to the predisposition to perceive noisy events. Annoyance is an attitudinal dimension indicating the extent to which noises are evaluated unfavourably.(20) About 20-30% of individuals self-describe as noise sensitive. Although noise sensitivity does not differ by sex, it tends to increase with age.(21) Noise-sensitive individuals have noise "annoyance thresholds" approximately 10 dB lower than noise tolerant individuals(22) and usually react to environmental sound more easily, evaluate it more negatively, and experience stronger emotional reactions compared to noise tolerant people.(23) People who are noise sensitive are more likely than others to report annoyance due to exposure to sound at low and moderate intensity.(24) Noise sensitivity and annoyance are usually measured by self-report questionnaires. In this study, we will selectively recruit subjects who report increased noise sensitivity and measure annoyance from study exposures in each study arm.

2. Study Objectives

To investigate whether one month infrasound exposure, compared with the sham exposure, is associated with impaired sleep quality (the primary outcome, measured as wake after sleep onset, WASO), an excess of symptoms that have been attributed to Wind Turbine Syndrome, annoyance, sleepiness, impaired neurobehavioural and neurocognitive performance, , increased arterial stiffness and increased blood pressure (secondary outcomes).

Secondly, to investigate whether experiencing an excess of symptoms that have been attributed to WTS is related to baseline levels of stress and anxiety.

A complementary short-term laboratory-based study is underway to measure the short term health effects of exposure to infrasound, sham (negative control) and traffic noise (positive control). **http://www.ANZCTR.org.au/ACTRN12617000001392.aspx**

3. Experimental design

This community based randomised controlled trial has two parallel groups and will be conducted within the homes of Sydney participants:

1) simulated wind turbine sound (infrasound, test exposure)
2) absence of sound (sham, control exposure).

Participants will be randomised to either the infrasound or sham exposure. Two to four speakers that are visually identical but that deliver either infrasound or sham will be installed in the bedrooms of participants. Participants and research staff conducting clinical assessments will be blinded to the test and control exposure (as the infrasound is inaudible). The members of the team who will be unblinded are the acoustic engineers who install the speakers in the home, conduct checks and maintenance and the researcher responsible for the randomisation schedule.

The speakers will be in place for one month and clinical outcome assessments will be conducted one month after baseline measurements.

4. Methods: Participants, interventions, and outcomes

Study setting

The study will be conducted within homes in Sydney.

5. Eligibility criteria

5.1 Inclusion criteria

1. Aged 18 or above (**If you consent to participate in this study you agree that persons under the age of 18 will not be permitted to sleep in the bedroom where the speakers are installed**
2. Noise sensitive individuals -defined as Weinstein's Noise Sensitivity Scale (WNS) Score >58 (Appendix B)
3. Normal hearing assessed by telephone questionnaire and no hearing aid
4. Regular sleep of 5.5 hours / 24 hours for 7 days as demonstrated by actigraphy
5. Fluent in English, to be able to answer computerised questionnaires and undergo neurocognitive assessments in English

5.2 Exclusion criteria

1. Rotating shift worker
2. Planning to be away from home for more than a week during the study period
3. Major psychiatric disorders
4. Use of any hypnotic medications or other medications that interfere with sleep within the last month
5. Breastfeeding, pregnant or attempting to become pregnant women in the household
6. Young children (under 5 years) living in the home
7. Insomnia Severity Index score < 18

6. Study Interventions

Participants that meet the eligibility criteria will be randomised to either:

1) simulated wind turbine sound at 85dB Pk (infrasound, test exposure)
2) absence of sound (sham, control exposure).

Two to four 600mm x 600mm cube speakers (photo below) will be installed in the bedroom of each participant. For participant convenience, these speakers can be placed in variable configurations within the participant's bedroom. The speakers are wired together and are powered by a single cord that plugs into a domestic power point.

In addition to the speakers there will be a single microphone stand with an infrasound microphone attached. . The role of this microphone is to measure the level of infrasound (sound less than 20Hz and inaudible to the human ear) in the bedroom.

The speakers and microphone will operate continuously over the one month period of the study. By agreement with the participant, the acoustic engineer will schedule a mid study visit to the home to assess the correct functioning of the equipment. The acoustic engineer visits will be at baseline for speaker installation, at 2 weeks for speaker checks and at 4 weeks for speaker removal. All participants will be reimbursed for expenses associated with the use of electricity to run the speakers. The acoustic engineer will be unblinded to group allocation and will be the contact point for participants who want to discuss anything regarding the speakers, microphones, electricity consumption or other exposure related query, thus ensuring the participant and clinical assessment staff remain blinded to group allocation.

6.1 Discontinuing

Withdrawal criteria

Participants will be informed that they have the right to withdraw from the study at any time, without prejudice to any medical care (such that might be required if we incidentally identify a medical condition), and are not obliged to state their reasons. Additionally the investigator may withdraw a participant at any time for the following reasons:

- If any of the study exclusion criteria are diagnosed
- Protocol violations
- Adverse events

Discontinuation of the study

The study may be discontinued at any time on the advice of the responsible principal investigators on the basis of new information regarding safety. A Data Safety Monitoring Board has been constituted to provide advice to the investigator team with regard to participant safety (Section 15.1). Additionally, the study may be terminated if progress is unsatisfactory.

In the case of premature termination or suspension of the experiment, the investigator will inform the study participants and ensure appropriate follow up in the unlikely event this is required clinically. In addition, the appropriate ethics committee will be informed.

Procedure to withdraw

Participants with clinically significant abnormalities requiring discontinuation will be followed until recovery from the abnormality. If the study is discontinued for safety reasons, the investigators will contact all affected participants within a week to inform them of the termination of their involvement in the study. Participants discontinuing from the study may be replaced. A new participant number must be issued for the new participant.

If a participant fails to respond to telephone contact or is consistently unavailable for home visit, attempts will be made to ensure that the reason for not communicating is not an adverse event (bearing in mind that the participant is not obliged to state his/her reasons).

7. Outcomes

Primary outcome measure:

Changes in wake after sleep onset (WASO) as determined by 4 EEG channel polysomnography with portable recorder between baseline and one month. We will compare the differences between infrasound and sham sound.

Secondary outcome measures:

EEG parameters from the overnight sleep studies - Sleep latency, sleep staging, sleep stage shifts, arousal frequency and power spectral analysis for sleep microarchitecture analysis.

Tertiary Outcome Measures:

Neurocognitive tests (Section 12.8):

N-back
Tower of London

Cardiovascular and stress measures (Section 12.9):

Office blood pressure
Pulse wave velocity
Heart rate variability
Screening, Phenotyping and Explanatory Questionnaires and measures (Appendix A & B):

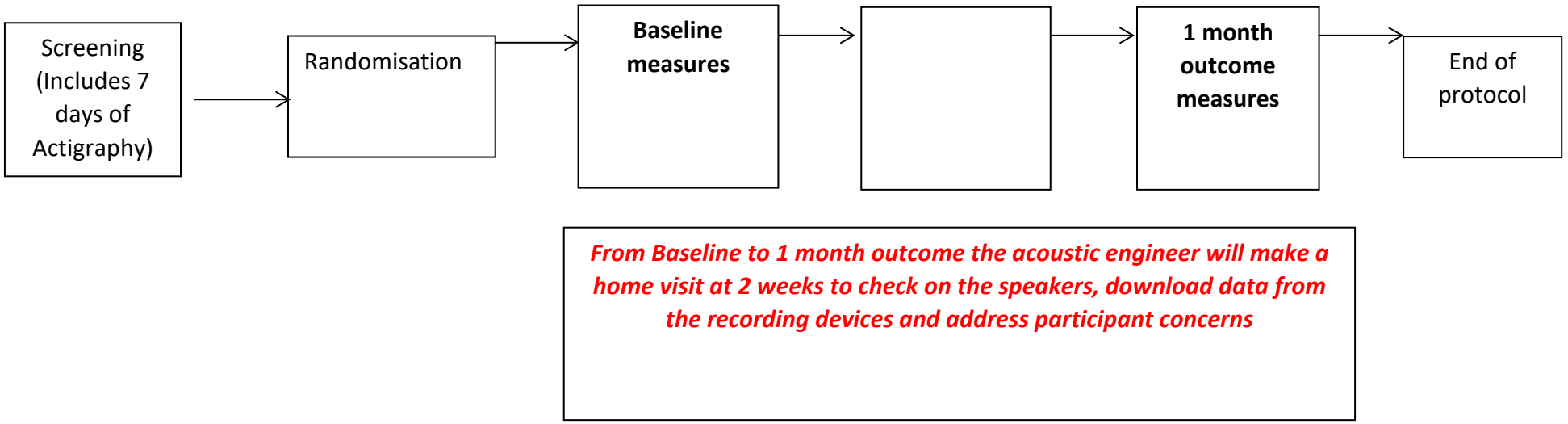
Insomnia Severity Index (ISI) questionnaire
Weinstein's Noise Sensitivity Scale (WNS) score
Depression Anxiety and Stress Scale (DASS-21)
Kessler 10 (K10)
Eysenck Personality Questionnaire-Revised (EPQ-R)
Noise Annoyance Scale
Symptom Visual Analogue Scales
Warwick Edinburgh Mental Well-being Scale
Medical history
Medication
Sleep Disorders and Patterns
Epworth Sleepiness Scale
Shift work questionnaire
Attitudes on Windfarms
Exit questionnaire

Table 1. Screening, Baseline and Outcomes Measurements

Item	Staff	Screening	Baseline	1 month
Screening - online				
Weinstein's Noise Sensitivity Scale (WNS)		X		
Cardiovascular, sleep, or neurological chronic illness			X	
Clinically significant sleep disorders		X		
Major psychiatric disorder		X		
Hypnotic or anti-psychotic medication		X		
Shift work Questionnaire		X		
Breastfeeding, Pregnant or planning pregnancy		X		
Child under the age of 5 years		X		
Insomnia Severity Index		X	X	X
Epworth Sleepiness Scale			X	X
DASS-21			X	X
Kessler-10			X	X
Attitudes on Wind farms			X	
Exit Questionnaire				X
Screening – home				
Actigraphy and Consensus sleep diary (7 nights)		X		
Hearing (via questions over the telephone)		X		
Clinical Assessments - home				
Sleep and Wake Measurements				
Home 4 EEG channel polysomnography (1 night)			X	X
Neurobehavioural and neurocognitive performance			X	X
Actigraphy (7 nights prior to PSG)			X	X
Sleep Disorders and Patterns Questionnaire			X	X
Cardiovascular and Stress measurements				
Height, Weight, Waist circumference			X	X
Office Blood Pressure			X	X
Pulse wave velocity			X	X
Annoyance and Wind Turbine Syndrome measurements				
Visual Analogue Scale questionnaire			X	X
Noise Annoyance Scale			X	X
Psychological measurements				
Eysenck Personality Questionnaire-Rev.			X	
Warwick Edinburgh Mental Well-being Scale (WEMWBS)			X	X

8. Participant timeline

Figure 1: Timeline for study protocol



8.1 Enrolment/screening

Screening of suitable participants will be undertaken in two phases. The first phase will be conducted via an online screening questionnaire. The second phase of home screening will combine a non-invasive technique (wrist actigraphy and sleep diary) for the at-home measurement of normal sleep/wake cycles and telephone screening by a member of the study research team.

Phase 1: Online Screening

Online screening procedure is described in 12.3

All participants who attempt stage 1 of screening (i.e. receive a unique login, see 13.2.2) will be assigned with a sequential ID.

Phase 2: Home Screening

The home screening procedure is described in 12.3.1

If shown eligible on the online screening, participants will be contacted by a member of the research team to ask whether they have any hearing difficulty, whether they wear a hearing aid and for the researcher to assess whether the participant demonstrated any difficulty with hearing during the telephone call. We will also explain that we will send an Actiwatch 2, a painless watch-like device worn around the wrist to monitor sleep and wake cycles and activity patterns (body movement and ambient light). Accompanying the Actiwatch 2, participants will be sent and asked to fill out a sleep diary self-assessing their sleep whilst at home. Participants will be asked to wear the Actiwatch 2 and complete the sleep diary for at least 7 days and then to return this in the supplied Express Post envelope.

If a participant is willing and eligible they will then have the study fully explained to them and will be given the opportunity to ask questions before they give written informed consent to enrol in the study at the baseline home visit.

8.2 Baseline, and 1 month home visits

Eligible participants who have given informed consent will have a baseline visit scheduled during which time they will complete a range of clinical assessments as described in Table 1.

Outcome measures will be collected at a 1 month home visit. The visit will be conducted at a convenient time for the participant. Prior to the 1 month outcome assessment the participant will be sent an Actiwatch 2 to wear for one week prior to the visit. They will also have an overnight polysomnography (sleep study) performed. The research assistant will visit the home in the evening to connect the leads for the study. They will also provide instructions to the participants. The research assistant will return the next day or day after to collect the equipment.

8.3 Infrasound or Sham speaker installation and monitoring

The acoustic engineer will schedule a visit to the home soon after baseline testing has been completed. At this visit, either infrasound or sham speakers will be installed into the bedroom of the participant. In addition to the 2 or 4 x 600mm cube speakers we will place a monitoring box and 1 infrasound microphone in the bedroom.

The acoustic engineer is unblinded and will advise participants that if they have any concerns about the speakers that they should contact him directly and not discuss this with other members of the team who do not know what type of speaker is installed in the bedroom. Additionally, the participants will be informed that their electricty bill may increase and that they will be reimbursed for this expense. Again, this is to be discussed with the unblinded acoustic engineer who installed the speakers and not any other member of the team.

The acoustic engineer will arrange a visit to the home of participants at two weeks to check that the speakers are performing as designed and that the monitoring equipment is collecting infrasound or sham sound exposure information. He will download data and bring this back to Woolcock Institute for secure storage.

8.4 Reimbursement

Participants will be fully reimbursed for the additional cost of electricity for running the speakers and microphones. We anticipate that this amount will be in the range of $10 to $20. We will offer a payment of $500 to cover electricity and the inconvenience of having the speakers installed in the home and for participating in the home testing for all participants involved in this study.

9. Sample size

From previous studies, the between-subject standard deviation in wake after sleep onset (WASO) is conservatively estimated at 20 minutes. Most trials of treatments for insomnia, for instance, regard a change of 15 minutes or more in WASO as being clinically meaningful. A sample size of 120 participants (which includes allowance for 22 dropouts) will have 85% power to detect a 0.25 effect size (Cohen's f).

10. Recruitment

Number and source of participants

The target number of participants is 120. This will provide 60 participants in the infrasound group and 60 participants in the sham group.

Participants will be found by public advertising in local newspapers, community radio, television media and social media through the Woolcock website and its database of research volunteers which will direct all volunteers to the online screening website (Appendix A). We will also include a letterbox drop to homes within a 5 km radius of Glebe.

11. Methods: Assignment of interventions

11.1 Randomisation

Participants will be randomised to either infrasound or sham through the use of a pre-programmed randomization plan from http://www.randomization.com. All study personnel who collect clinical outcomes from participants will be blinded to group allocation. The only unblinded personnel will be the acoustic engineer and two senior chief investigators who independently check that the randomisation schedule is being implemented as designed.

11.2. Blinding

Expectations on the part of participants and investigators may influence the effect of the exposure (infrasound) and, more particularly, may influence the measurement of those effects, especially the subjective (self-reported) outcomes. To avoid the potential for this measurement bias, it is important that both participants and the investigators who are measuring outcomes are blinded to the intervention group. Fortunately, as infrasound is, by definition, inaudible, this is readily achieved by the use of a sham device that appears the same as the infrasound device, but which does not produce any sound. Only the unblinded acoustic engineer will have knowledge of the exposure and they will never disclose this group allocation to the participants or staff/investigators who interact with participants.

12. Methods: Description of study procedures

12.1 Informed consent

Each potentially eligible participant will be informed of the study's objectives and overall requirements by the lead study coordinator or one of the principal investigators using the participant information sheet and informed consent form, and they will be provided with a copy of the forms. If the participant is willing to participate in the study, they will be requested to give written, witnessed, informed consent.

12.2 Simulated infrasound waveform and sham infrasound

The infrasound attributable to wind turbines will be simulated using a 0.8 Hz trapezoidal-shaped waveform with 16 harmonics (Figure 2). Conventional audio systems are not capable of generating sound levels at 0.8 Hz. Therefore, a purpose built apparatus will be utilised (Figure 2).

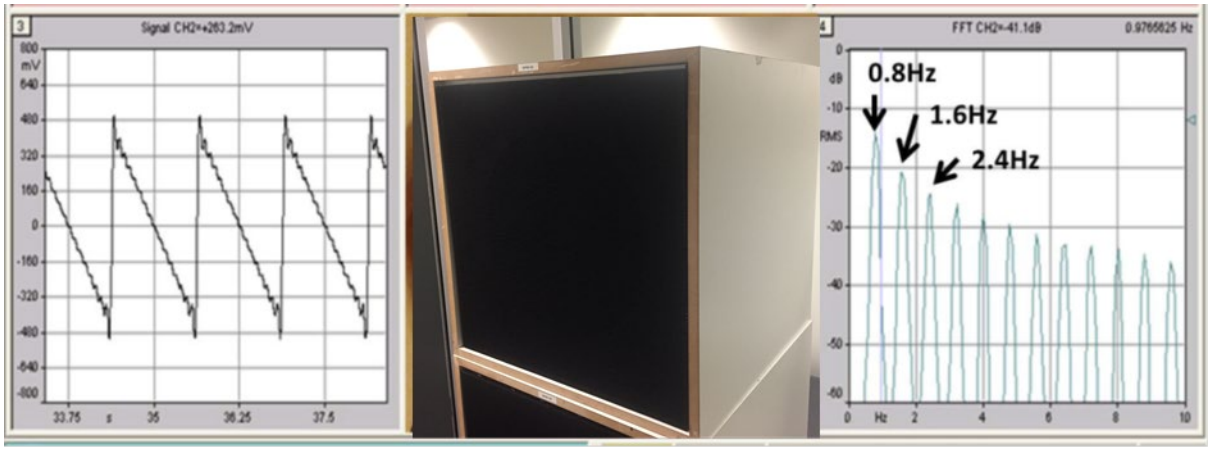


Figure 2. The Walker Speaker Boxes and the Simulated Spectrum

The apparatus generates the required waveform using two 18” sub-woofer drivers in a timber enclosure. Two to four 18” JBL high power sub-woofers will be used, each constructed separately in timber boxes with integral power amplifiers. . The separating gap between the enclosures is open on all four sides of each infrasound cube (i-cube) from which the infrasound pressure waveform will be emitted. The 2-4 x 600mm i-cubes will be placed in convenient corner locations within master bedroom. The i-cubes will be electronically connected by cable to enable the infrasound waveform signature to be fed to both speakers simultaneously. Sham units will be constructed to appear identical to the active (infrasound-emitting) i-cubes, but will not emit any audible sound or infrasound.

12.2.1 Monitoring infrasound exposure

Sound level in the master bedroom will be measured by a low frequency microphone (Fig 3) type G.R.A.S. 40AZ which is a ½" Pre-polarised Free-Field Microphone connected to a G.R.A.S. Type 26CG ¼" Low Frequency CCP Preamplifier. The G.R.A.S. 40AZ microphone has a frequency response of 0.5Hz to 20 kHz (+/- 2dB) which encompasses the range of the study. As well, a G.R.A.S. 12AL 1-Channel CCP Power Module, custom built 50Hz low pass filter/amplifier and Graphtec GL220 data logger with USB hard drive will be utilised for data acquisition. The infrasound will be recorded on the USB hard drive for post processing. Peak sound levels will be measured for each 15 minute interval. All equipment will be certified as conforming to appropriate international standards at the NATacoustic NATA registered laboratory in Sydney. Only the unblinded acoustic engineer will have access to this data.

Figure 3. Microphone stand with infrasound microphone

12.3 Online screening website

Through various recruitment strategies participants will be referred to an online website to register their interest (Appendix A) where they will be asked to register with their details (Name, Phone number, Email address and Postcode) and in return, participants will be sent a unique login and instructions to complete an online questionnaire for this study that will be used as a tool to help screen and phenotype participants. The online questionnaire is a series of questionnaires (Appendix A & B) asking about general health, medication use, medical history and sleeping patterns. Furthermore, participants will answer various questionnaires regarding their psychological wellbeing which will further assist in the decision determining the suitability for each participant. Some questionnaires will be automatically scored using standardised scoring algorithms that will help in excluding

participants who are unsuitable and flagging participants who require a decision to be made by members of the research team. Participants will be asked to give consent before beginning the questionnaire for screening online and, if eligible, at a home visit. Participants who are ineligible because they are not noise sensitive will be informed at the end of the questionnaire. If participants are ineligible for any other reason they will be informed via telephone by one of the research team.

12.3.1 Home screening

If shown eligible on the online screening, participants will be contacted by a member of the research team to ask whether they have any hearing difficulty, whether they wear a hearing aid and for the researcher to assess whether the participant demonstrated any difficulty with hearing during the telephone call.. We will also explain that we will send an Actiwatch 2, a painless watch-like device worn around the wrist to monitor sleep and wake cycles and activity patterns (body movement and ambient light). Accompanying the Actiwatch 2, participants will be sent and asked to fill out a sleep diary self-assessing their sleep whilst at home. Participants will be asked to wear the Actiwatch 2 and complete the sleep diary for at least 7 days and then to return this in the supplied Express Post envelope

12.4 Psychological and psychiatric health

The following questionnaires will be measured baseline and at one month (see Appendix B)

1. Noise Annoyance Scale
2. Symptom Visual Analogue Scales
3. Warwick Edinburgh Mental Well-being Scale (WEMWBS)
4. Depression Anxiety and Stress Scale (DASS-21)
5. Insomnia Severity Index (ISI)
6. Eysenck Personality Questionnaire – Revised (EPQ-R)
7. Attitudes on Wind farms
8. Kessler (K10)

12.5 General health assessment

Anthropometric measurements such as height, weight, waist circumference and blood pressures will be taken at the face to face home visit at baseline and the one month outcome assessment visits.

12.6 Polysomnography (PSG) (Appendix E)

Home-based polysomnography (PSG) for assessment of sleep and sleep quality will include multichannel recording including oximetry, ECG, EEG, EMG, flow and chest and abdomen movement using a small portable recorder (Alice PDx, Philips Respironics). A trained researcher will attach equipment in the late afternoon and retrieve it within the next two days. Polysomnography data will be analysed by a single core laboratory at the Woolcock Institute of Medical Research (The University of Sydney, NSW, Australia) using standardised analysis and reporting protocols.

12.7 Neurocognitive Assessments (Appendix F)

The computerised neurocognitive test battery will include the N-back and the Tower of London test. Neurocognitive tests will occur at baseline and one month clinical assessments.

12.7.1 N-back (2-back)

This test involves the participant monitoring a series of stimuli and requires them to respond whenever a stimulus is presented that is the same location as the one presented n trials previously, where n is a pre-specified integer, usually 1, 2, or 3. The task requires on-line monitoring, updating, and manipulation of remembered information and is therefore assumed to place great demand on a number of key processes within working memory.

12.7.2 Tower of London

This computerised test involves the presentation of two different arrangements of coloured balls on the monitor. The subject's task is to rearrange the first array of balls so that it matches the second array of balls using the minimum number of moves possible with the mouse. The positioning of the balls is constrained to the location of three pegs in each display. This test demands that the sequence of moves is carefully planned in advance before attempting the first move. Failure to engage in advanced planning of the sequence will result in initial moves blocking subsequent ball moves. This test involves using "executive" function, specifically forward planning, to solve a problem. Accuracy, determined as the number of moves, and speed, using time, variables can be obtained.

12.8 Cardiovascular and stress measures (Appendix G)

12.8.1 Pulse wave Velocity

Pulse Wave velocity is the gold standard for measuring aortic stiffness. The measurement is a painless, non-invasive test and entails inflating a cuff around a fully clothed thigh whilst simultaneously placing a pressure probe on the carotid artery of the neck across the skin. The test will require the participant to maintain a resting period of 10 minutes and 5 minutes measuring periods. This measurement will be recorded whilst in the exposure of the experimental noise conditions.

12.8.2 Heart rate variability

This will be measured through ECG leads which are attached during routine overnight sleep study. This will be analysed using PRANA® Software Suite.

12.9 Insomnia Severity Index (ISI) questionnaire (see Appendix B)

The ISI is a 7-item patient reported outcome measure that probes the severity of both the night time and daytime impact of insomnia and takes approximately 3 minutes to complete. Each item uses a 5-point Likert scale to capture a rating (0 = no problem; 4 = very severe problem) which add up to: no insomnia (0 – 7); sub-threshold insomnia (8 – 14); moderate insomnia (15 – 21); and severe insomnia (22 – 28). It will be completed at baseline and one month clinical assessments.

13. Data Management

Data collected in the study will be in written and computerised formats. Paper records shall be securely stored in locked cabinets at the Woolcock Institute of Medical Research for up to 15 years following the end of the study. Computerised data will be stored and backed-up on a secure cloud based, individual password protected database system (Research Tools^{TM}) which logs all access or changes to data back to individual users who will be given only access or change privileges to data which they require for their role. During data collection, only investigators named at the front of this protocol, the unblinded study statistician and the data safety monitoring committee will be allowed access to the study data under the supervision of the Principal Investigators. After study completion, a non-identifiable dataset (does not include information that could help identify a participant such as date of birth, address or ethnicity) may be published in an open access data repository. All data will be re-identifiable as, once randomised into the study, participants will be allocated an individual study code number. The master coding sheet will be kept in a password encrypted file and only investigators and research staff will have access to it. However, if needed, each individual will be able to be re-identified.

14. Statistical Methods

Generalised linear mixed models will be utilised for statistical analysis. WASO will be the dependent variable in the primary analysis. All other outcomes will be tested separately as dependent variables. Exposure (infrasound vs sham) will be the main fixed effect. As multiple outcome measures will be made (at baseline and at one month follow-up) a "time" fixed effect will also be included and exposure-by-time interactions will be tested. The differences specifically at the one month time period will be the primary endpoint. In sub-analyses we will also test whether changes in outcomes are influenced by whether people thought windfarms have health effects (expectancy) to establish whether this attribute modifies the propensity to experience WTS symptoms with exposure

15. Methods: Monitoring

15.1 Data monitoring

Because infrasound like this has not been used in experiments of longer than 2 hours duration a Data Safety Monitoring Board has been convened. The DSMB will oversee participant safety in both the laboratory study (Protocol No X16-0073 & HREC/16/RPAH/91) and this community based study by reviewing unblinded accumulated safety data pertaining to infrasound. As at the date of this protocol we have not had any serious adverse events in our laboratory study where 19 participants have completed the study.

16. Adverse Events Reporting

Collection of adverse events will occur throughout the study.
Serious adverse events (SAE) are defined as any untoward medical occurrence that:

- Results in death
- Is an immediately life-threatening condition
- Requires hospitalisation or prolongs hospitalisation
- Results in persistent or significant disability/incapacity
- Is a congenital anomaly/birth defect
- Results in any other important medical condition.
  The Ethics Committee will be notified of any SAE within 72 hours.

17. Auditing

The study will not be externally audited

18. Ethics and dissemination

18.1 Study conduct/ethics approval

The study will be conducted under the ethical jurisdiction of the Sydney Local Health District (SLHD) Ethics Committee at Royal Prince Alfred Hospital and will be performed in accordance with the Declaration of Helsinki,[27] the Australian Good Clinical Research Practice Guidelines[28] (Commonwealth of Australia, 1991) and the guidelines of the National Health and Medical Research Council for human research.[29]

19. Protocol amendments

Any amendments to the protocol will be made in writing to the SLHD Ethics Committee after discussion with all co-investigators, and then be communicated to all participants, whereby further consent will be obtained for any protocol amendments.

20. Confidentiality

Participant data will be identified by a code number that will be allocated after the participant gives consent to participate in the study. The key linking the participant's identity to the relevant code will be stored in a password encrypted file that will not be accessible from the internet. Storage of the data collected will adhere to the University regulations & the Australian Code for the Responsible Conduct of Research. A dataset containing individual participant data will be published online in conjunction with the academic publication of these data. That dataset will be non-identifiable and will not contain any personal information about the participant that could be used to identify them (including age, gender, ethnicity, address or postcode).In any publication and/or presentation, information will be provided in such a way that participants cannot be identified, except with their written, informed permission. Any information obtained for the purpose of this research that could identify participants will be treated as confidential and securely stored.

21. Declaration of Interests

None of the investigators have any pecuniary interest or academic conflict of interests in the outcomes of this study.

22. Access to data

During the study only investigators and members of the study team will have access and control to any data collected from participants. There are no contractual agreements that would limit access or control of the study to the investigators. After the study, a non-identified dataset will be made available online in a data repository. Making data available in such a way is increasingly becoming an expectation of research teams who conduct publicly funded research.

23. Ancillary and post-trial care

As this is not a clinical trial for a medical condition and does not involve any treatment, no clinical follow up will be routinely offered to participants. If however any harm is caused during this protocol or a medical condition becomes apparent, then medical follow-up will be arranged with either a member of the clinical research team or the participant's normal medical practitioner.

24. Dissemination policy

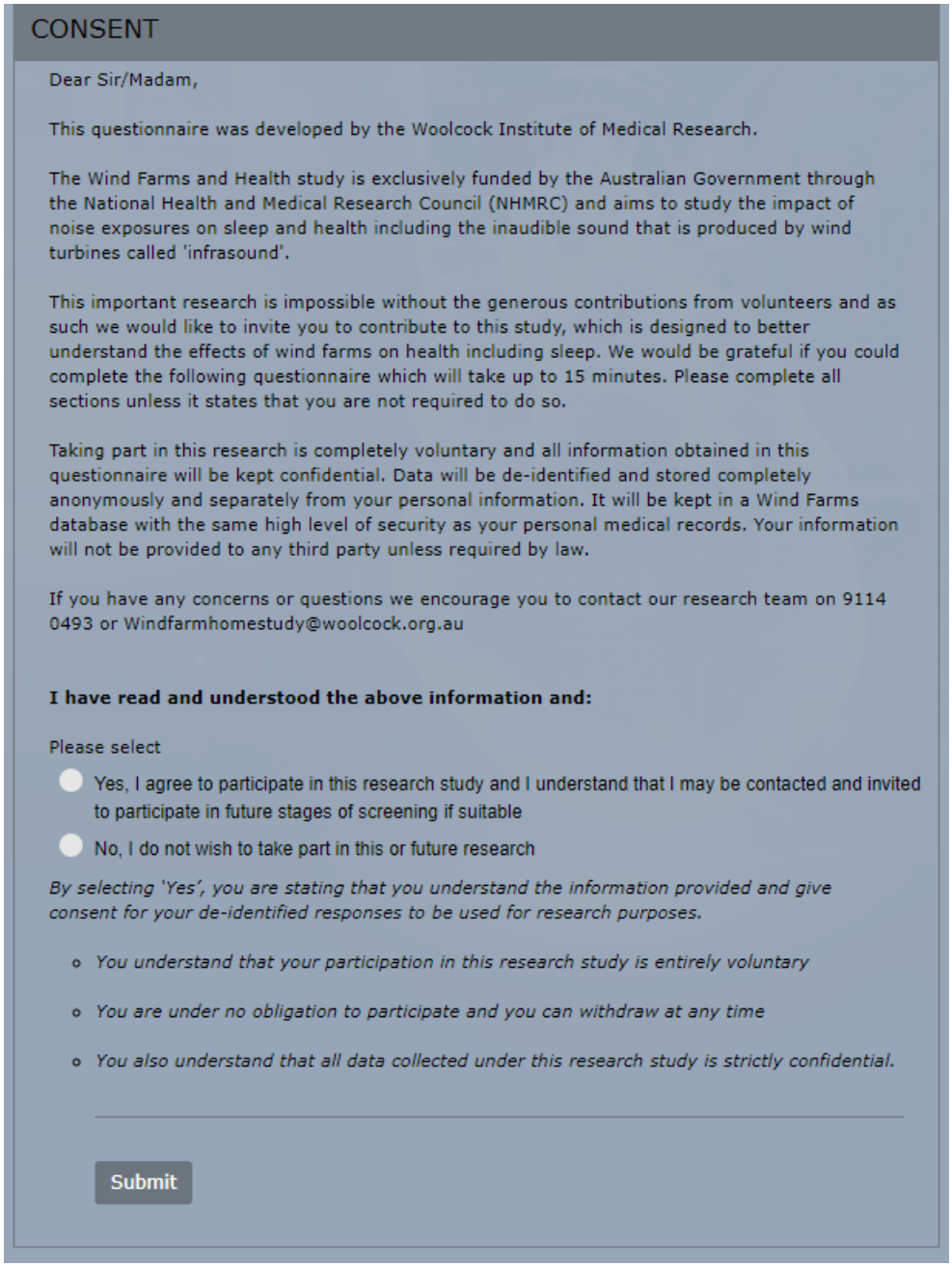
Study results will be published in peer-reviewed journals and participants will be made aware of these following publication should they desire. The publication committee consists of Prof Marks & Grunstein, A/Prof Marshall and Drs Toelle and Tonin. They shall be responsible for the formulation and execution of publication plans. Authorship on any manuscripts will be at the discretion of the publication committee.

25. Appendices

A. Online Registration, Consent and Screening Questionnaires

I. www.windfarmstudy.com

II. Online Screening and Consent Form



CONSENT

Dear Sir/Madam,

This questionnaire was developed by the Woolcock Institute of Medical Research.

The Wind Farms and Health study is exclusively funded by the Australian Government through the National Health and Medical Research Council (NHMRC) and aims to study the impact of noise exposures on sleep and health including the inaudible sound that is produced by wind turbines called 'infrasound'.

This important research is impossible without the generous contributions from volunteers and as such we would like to invite you to contribute to this study, which is designed to better understand the effects of wind farms on health including sleep. We would be grateful if you could complete the following questionnaire which will take up to 15 minutes. Please complete all sections unless it states that you are not required to do so.

Taking part in this research is completely voluntary and all information obtained in this questionnaire will be kept confidential. Data will be de-identified and stored completely anonymously and separately from your personal information. It will be kept in a Wind Farms database with the same high level of security as your personal medical records. Your information will not be provided to any third party unless required by law.

If you have any concerns or questions we encourage you to contact our research team on 9114 0493 or Windfarmhomestudy@woolcock.org.au

I have read and understood the above information and:

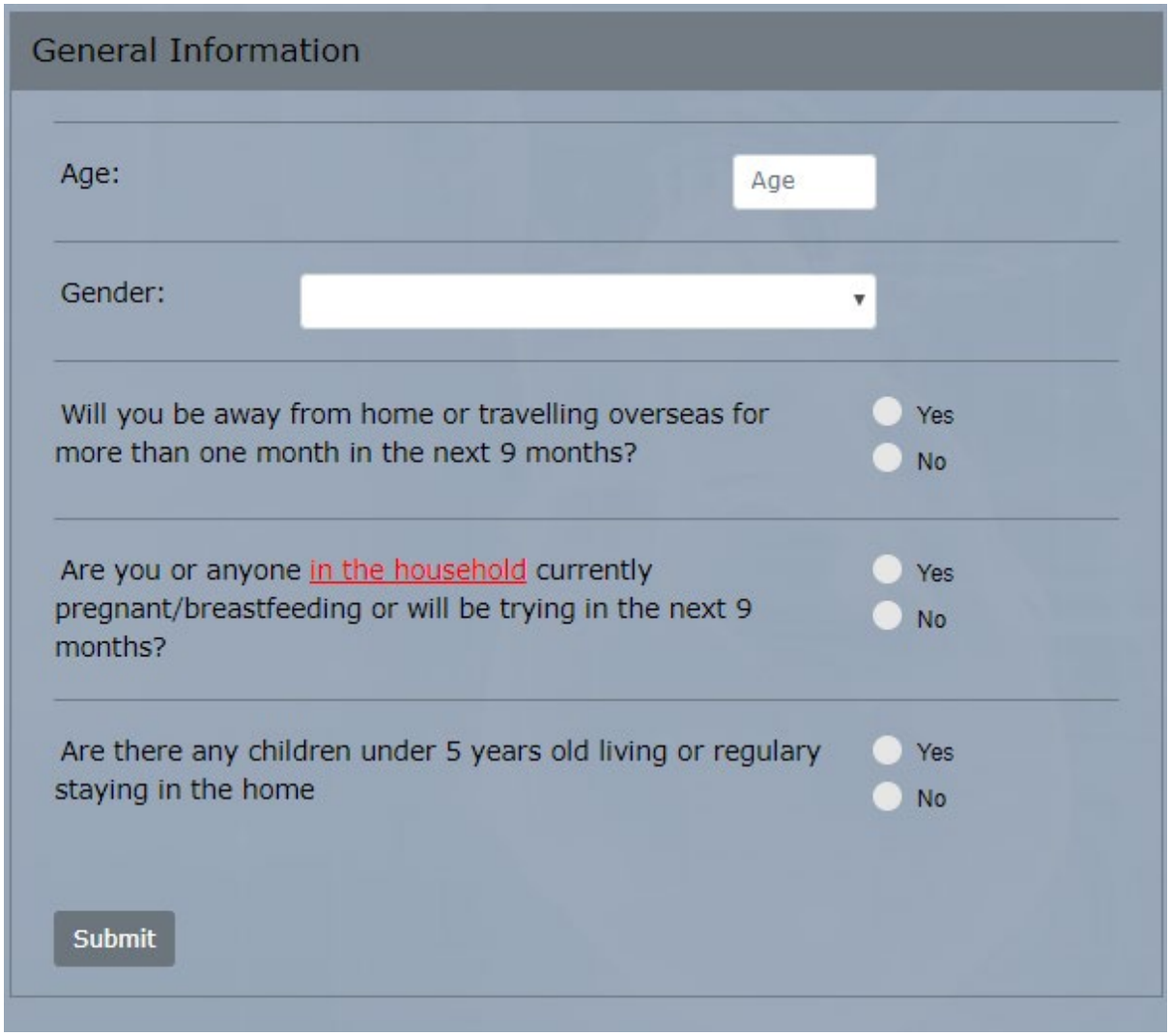
Please select

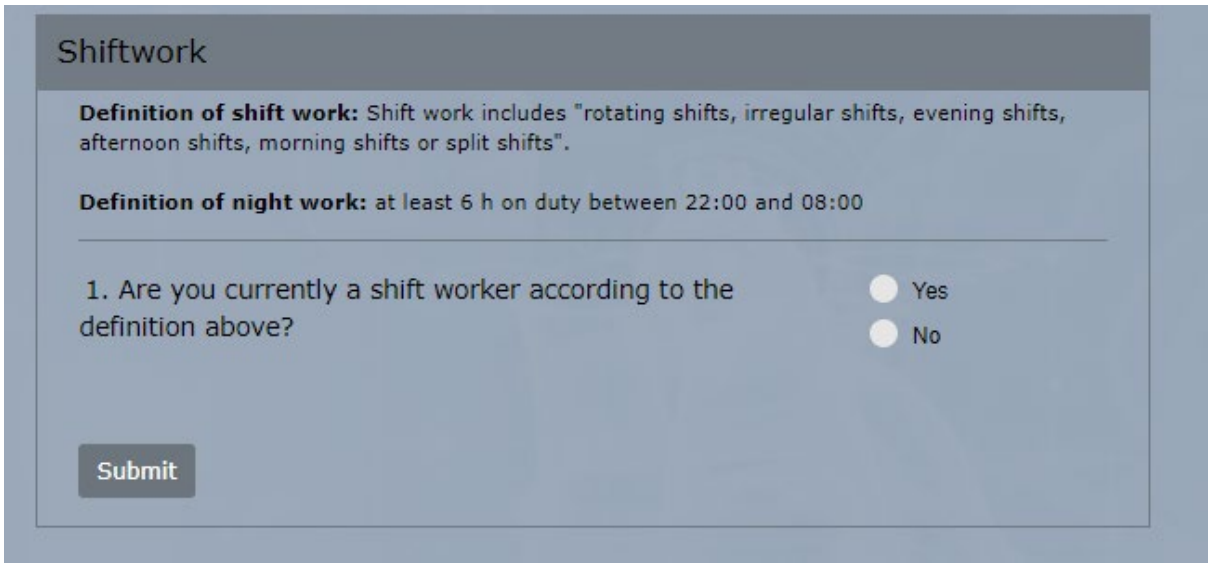
- ○ Yes, I agree to participate in this research study and I understand that I may be contacted and invited to participate in future stages of screening if suitable
- ○ No, I do not wish to take part in this or future research

By selecting 'Yes', you are stating that you understand the information provided and give consent for your de-identified responses to be used for research purposes.

- *You understand that your participation in this research study is entirely voluntary*
- *You are under no obligation to participate and you can withdraw at any time*
- *You also understand that all data collected under this research study is strictly confidential.*

Submit


General Information
Age:
Age
Gender:
Will you be away from home or travelling overseas for more than one month in the next 9 months?
Yes
No
Are you or anyone in the household currently pregnant/breastfeeding or will be trying in the next 9 months?
Yes
No
Are there any children under 5 years old living or regulary staying in the home
Yes
No
Submit


Shiftwork
Definition of shift work: Shift work includes "rotating shifts, irregular shifts, evening shifts, afternoon shifts, morning shifts or split shifts".
Definition of night work: at least 6 h on duty between 22:00 and 08:00
1. Are you currently a shift worker according to the definition above?
Yes
No
Submit

Weinstein Noise Sensitivity Score

Instructions: Click on the corresponding number to how well you agree or disagree

1. I wouldn't mind living on a noisy street if the apartment I had was nice

AGREE 1 2 3 4 5 6 DISAGREE

2. I am more aware of noise than I used to be

AGREE 6 5 4 3 2 1 DISAGREE

3. No one should mind much if someone turns up his stereo full blast once in a while

AGREE 1 2 3 4 5 6 DISAGREE

4. At movies, whispering and crinkling candy wrappers disturbs me

AGREE 6 5 4 3 2 1 DISAGREE

5. I am easily awakened by noise

AGREE 6 5 4 3 2 1 DISAGREE

6. If it's noisy where I'm studying, I try to close the door or window or move someplace else

AGREE 6 5 4 3 2 1 DISAGREE

7. I get annoyed when my neighbours are noisy

AGREE 6 5 4 3 2 1 DISAGREE

8. I get used to most noises without much difficulty

AGREE 1 2 3 4 5 6 DISAGREE

9. How much would it matter to you if an apartment you were interested in renting was located across from a fire station

A LOT 6 5 4 3 2 1 NOT MUCH

10. Sometimes noises get on my nerves and get me irritated

AGREE 6 5 4 3 2 1 DISAGREE

11. Even music I normally like will bother me if I'm trying to concentrate

AGREE 6 5 4 3 2 1 DISAGREE

---

12. It wouldn't bother me to hear the sounds of everyday living from my neighbours (footsteps, running water etc.)

AGREE 1 2 3 4 5 6 DISAGREE

---

13. When I want to be alone, it disturbs me to hear outside noises

AGREE 6 5 4 3 2 1 DISAGREE

14. I'm good at concentrating no matter what is going on around me

AGREE 1 2 3 4 5 6 DISAGREE

---

15. In a library, I don't mind if people carry on a conversation if they do it quietly

AGREE 1 2 3 4 5 6 DISAGREE

16. There are often times when I want complete silence

AGREE 6 5 4 3 2 1 DISAGREE

---

17. Motorcycles ought to be required to have bigger mufflers

AGREE 6 5 4 3 2 1 DISAGREE

---

18. I find it hard to relax in a place that's noisy

AGREE 6 5 4 3 2 1 DISAGREE

19. I get mad at people who make noise that keeps me from falling asleep or getting work done

AGREE 6 5 4 3 2 1 DISAGREE

---

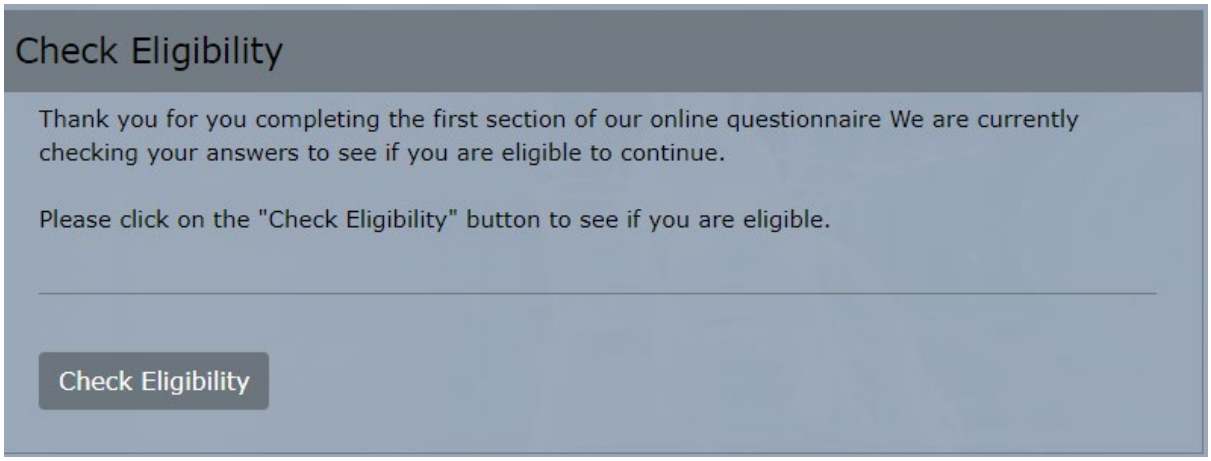
20. I wouldn't mind living in an apartment with thin walls

AGREE 1 2 3 4 5 6 DISAGREE

21.I am sensitive to noise

AGREE 6 5 4 3 2 1 DISAGREE

Submit

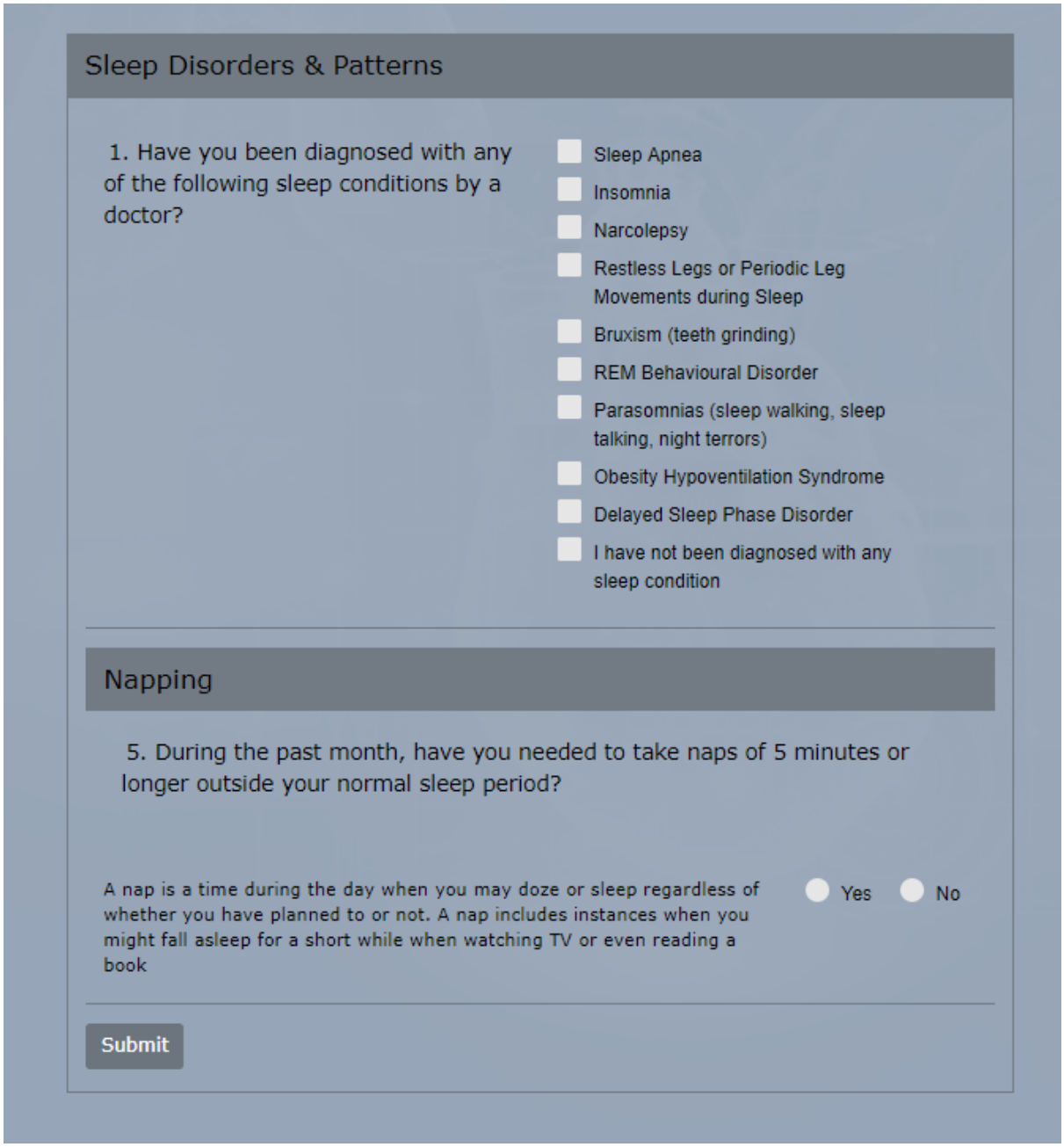

Check Eligibility
Thank you for you completing the first section of our online questionnaire We are currently checking your answers to see if you are eligible to continue.
Please click on the "Check Eligibility" button to see if you are eligible.
Check Eligibility

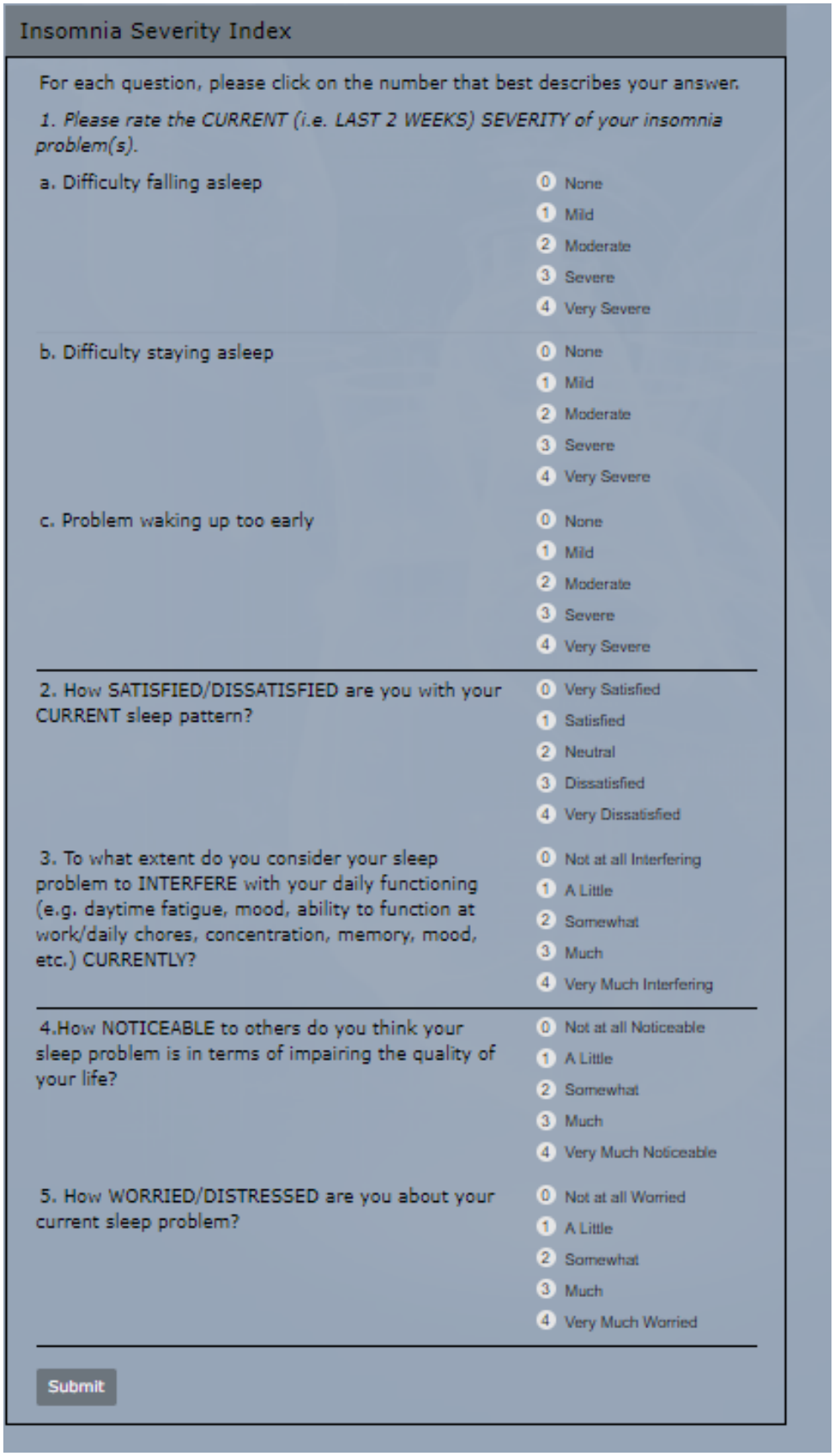
Anti-depressants

Agomelatine (e.g. Valdoxan)	☐ Are you currently taking / taken in the last month
Citalopram (e.g. Cipramil, Talam)	☐ Are you currently taking / taken in the last month
Escitalopram (e.g. Lexapro, Lexam)	☐ Are you currently taking / taken in the last month
Fluoxetine (e.g. Prozac, Lovan)	☐ Are you currently taking / taken in the last month
Lithium (e.g. Lithicarb, Quilonum)	☐ Are you currently taking / taken in the last month
Mirtazapine (e.g. Avanza, Axit)	☐ Are you currently taking / taken in the last month
Paroxetine (e.g. Aropax)	☐ Are you currently taking / taken in the last month
Sertraline (e.g. Zoloft)	☐ Are you currently taking / taken in the last month
Venlafaxine (e.g. Efexor)	☐ Are you currently taking / taken in the last month

Stimulants or Weight Reducing medications

Dexamphetamine	☐ Are you currently taking / taken in the last month
Methylphenidate (e.g. Ritalin, Concerta)	☐ Are you currently taking / taken in the last month
Modafinil (e.g. Modavigil, Provigil)	☐ Are you currently taking / taken in the last month


Sleep Disorders & Patterns
1. Have you been diagnosed with any of the following sleep conditions by a doctor?
Sleep Apnea
Insomnia
Narcolepsy
Restless Legs or Periodic Leg Movements during Sleep
Bruxism (teeth grinding)
REM Behavioural Disorder
Parasomnias (sleep walking, sleep talking, night terrors)
Obesity Hypoventilation Syndrome
Delayed Sleep Phase Disorder
I have not been diagnosed with any sleep condition
Napping
5. During the past month, have you needed to take naps of 5 minutes or longer outside your normal sleep period?
A nap is a time during the day when you may doze or sleep regardless of whether you have planned to or not. A nap includes instances when you might fall asleep for a short while when watching TV or even reading a book
Yes
No
Submit



Insomnia Severity Index

For each question, please click on the number that best describes your answer.

1. Please rate the CURRENT (i.e. LAST 2 WEEKS) SEVERITY of your insomnia problem(s).

a. Difficulty falling asleep
0 None
1 Mild
2 Moderate
3 Severe
4 Very Severe

b. Difficulty staying asleep
0 None
1 Mild
2 Moderate
3 Severe
4 Very Severe

c. Problem waking up too early
0 None
1 Mild
2 Moderate
3 Severe
4 Very Severe

2. How SATISFIED/DISSATISFIED are you with your CURRENT sleep pattern?
0 Very Satisfied
1 Satisfied
2 Neutral
3 Dissatisfied
4 Very Dissatisfied

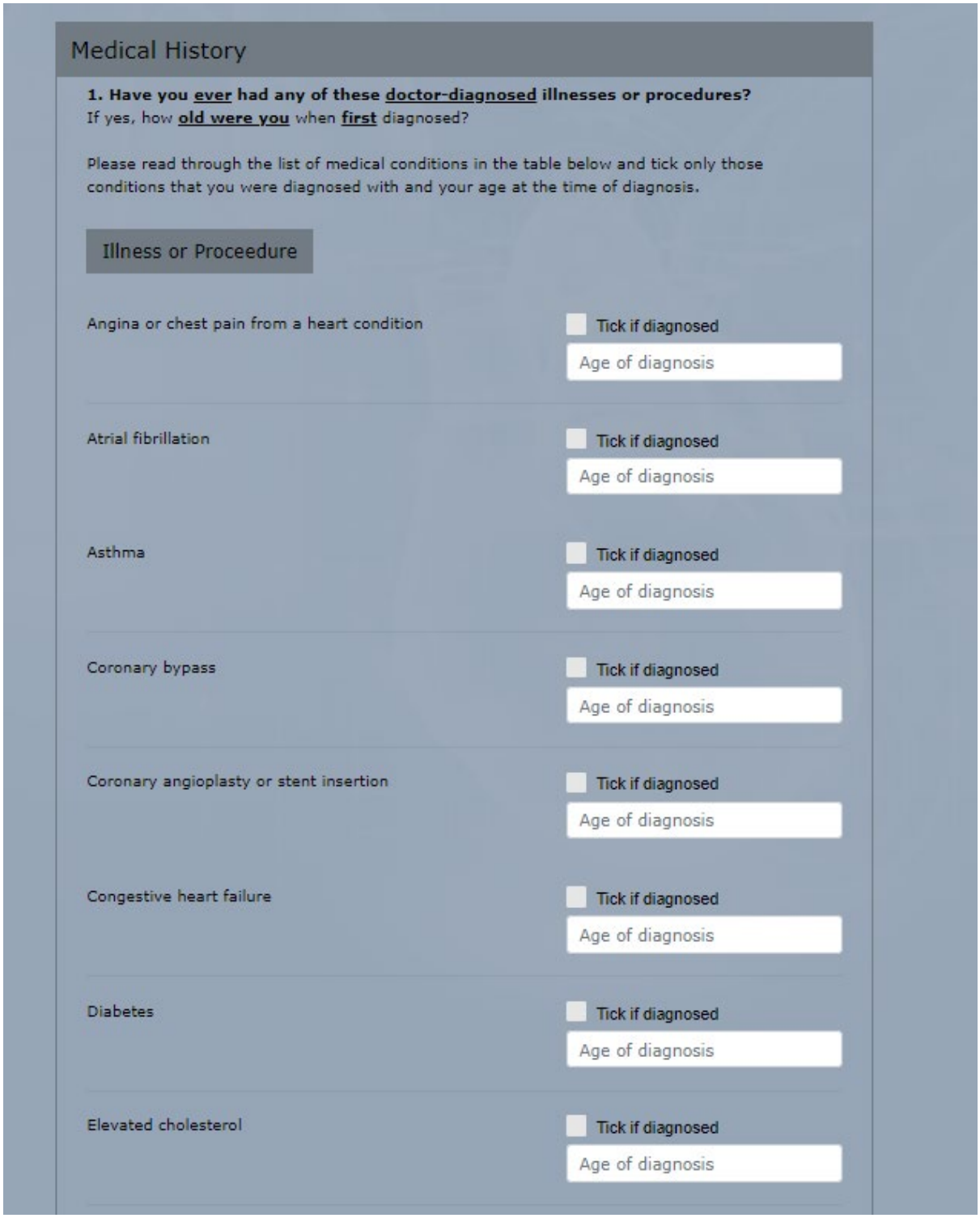
3. To what extent do you consider your sleep problem to INTERFERE with your daily functioning (e.g. daytime fatigue, mood, ability to function at work/daily chores, concentration, memory, mood, etc.) CURRENTLY?
0 Not at all Interfering
1 A Little
2 Somewhat
3 Much
4 Very Much Interfering

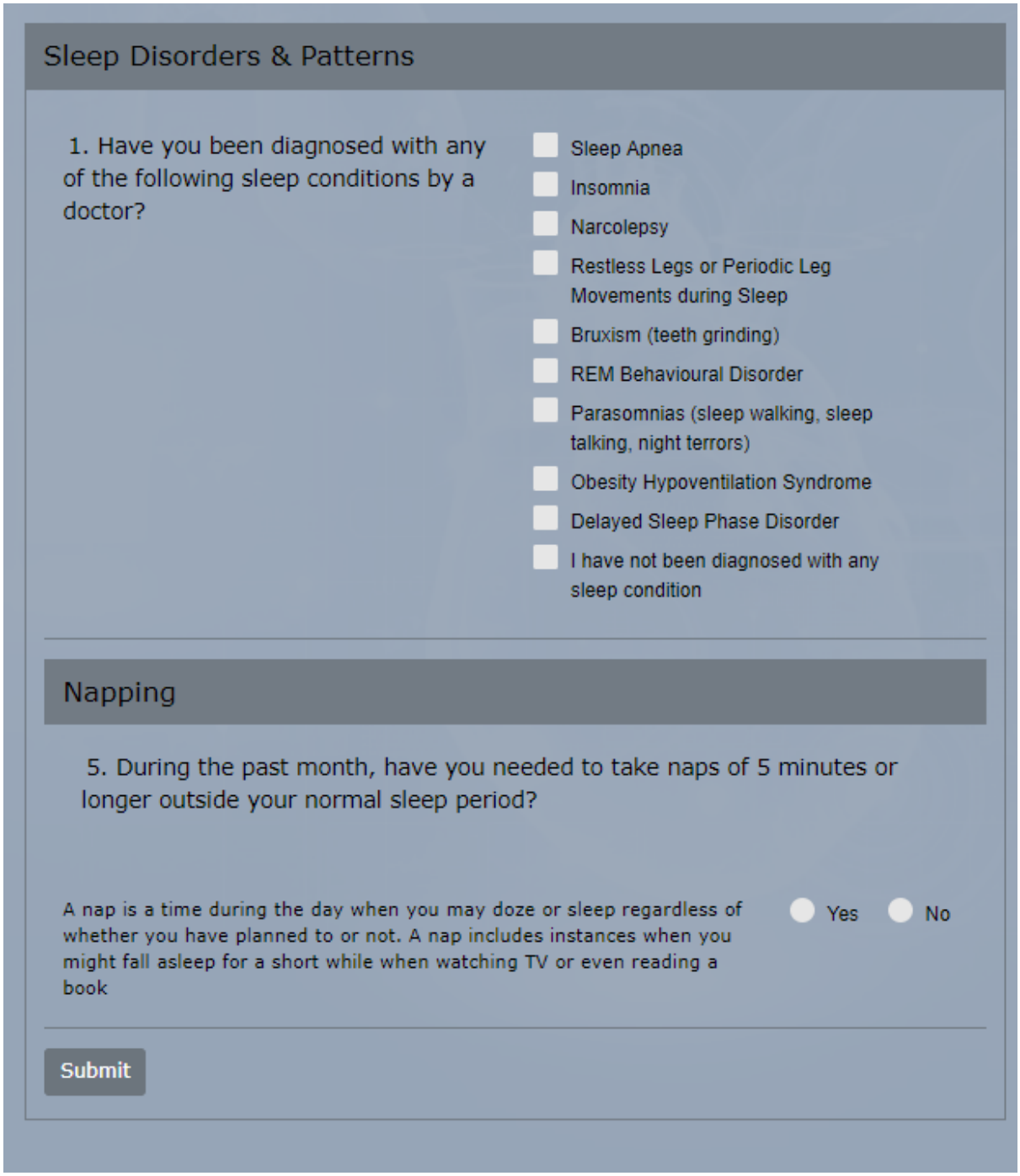
4.How NOTICEABLE to others do you think your sleep problem is in terms of impairing the quality of your life?
0 Not at all Noticeable
1 A Little
2 Somewhat
3 Much
4 Very Much Noticeable

5. How WORRIED/DISTRESSED are you about your current sleep problem?
0 Not at all Worried
1 A Little
2 Somewhat
3 Much
4 Very Much Worried

Submit

B. Baseline and one month outcome questionnaires


Medical History
1. Have you ever had any of these doctor-diagnosed illnesses or procedures?
If yes, how old were you when first diagnosed?
Please read through the list of medical conditions in the table below and tick only those conditions that you were diagnosed with and your age at the time of diagnosis.
Illness or Proceedure
Angina or chest pain from a heart condition
Tick if diagnosed
Age of diagnosis
Atrial fibrillation
Tick if diagnosed
Age of diagnosis
Asthma
Tick if diagnosed
Age of diagnosis
Coronary bypass
Tick if diagnosed
Age of diagnosis
Coronary angioplasty or stent insertion
Tick if diagnosed
Age of diagnosis
Congestive heart failure
Tick if diagnosed
Age of diagnosis
Diabetes
Tick if diagnosed
Age of diagnosis
Elevated cholesterol
Tick if diagnosed
Age of diagnosis


Sleep Disorders & Patterns
1. Have you been diagnosed with any of the following sleep conditions by a doctor?
Sleep Apnea
Insomnia
Narcolepsy
Restless Legs or Periodic Leg Movements during Sleep
Bruxism (teeth grinding)
REM Behavioural Disorder
Parasomnias (sleep walking, sleep talking, night terrors)
Obesity Hypoventilation Syndrome
Delayed Sleep Phase Disorder
I have not been diagnosed with any sleep condition
Napping
5. During the past month, have you needed to take naps of 5 minutes or longer outside your normal sleep period?
A nap is a time during the day when you may doze or sleep regardless of whether you have planned to or not. A nap includes instances when you might fall asleep for a short while when watching TV or even reading a book
Yes
No
Submit

The Warwick-Edinburgh Mental Well-being Scale (WEMWBS)

Below are some statements about feelings and thoughts.
Please tick the box that best describes your experience of each over the last 2 weeks

1. I've been feeling optimistic about the future	1 None of the time 2 Rarely 3 Some of the time 4 Often 5 All the time
2. I've been feeling useful	1 None of the time 2 Rarely 3 Some of the time 4 Often 5 All the time
3. I've been feeling relaxed	1 None of the time 2 Rarely 3 Some of the time 4 Often 5 All the time
4. I've been feeling interested in other people	1 None of the time 2 Rarely 3 Some of the time 4 Often 5 All the time

5. I've had energy to spare

1. None of the time
2. Rarely
3. Some of the time
4. Often
5. All the time

6. I've been dealing with problems well

1. None of the time
2. Rarely
3. Some of the time
4. Often
5. All the time

7. I've been thinking clearly

1. None of the time
2. Rarely
3. Some of the time
4. Often
5. All the time

8. I've been feeling good about myself

1. None of the time
2. Rarely
3. Some of the time
4. Often
5. All the time

9. I've been feeling close to other people

1. None of the time
2. Rarely
3. Some of the time
4. Often
5. All the time

Kessler - 10

For all questions, please circle the answer most commonly related to you. Questions 3 and 6 automatically receive a score of one if the proceeding question was "none of the time".

In the past four weeks:

1. About how often did you feel tired out for no good reason?

(1) None of the time
(2) A little of the time
(3) Some of the time
(4) Most of the time
(5) All of the time

---

2. About how often did you feel nervous?

(1) None of the time
(2) A little of the time
(3) Some of the time
(4) Most of the time
(5) All of the time

3. About how often did you feel so nervous that nothing could calm you down?

(1) None of the time
(2) A little of the time
(3) Some of the time
(4) Most of the time
(5) All of the time

---

4. About how often did you feel hopeless?

(1) None of the time
(2) A little of the time
(3) Some of the time
(4) Most of the time
(5) All of the time

---

5. About how often did you feel restless or fidgety?

(1) None of the time
(2) A little of the time
(3) Some of the time
(4) Most of the time
(5) All of the time

6. About how often did you feel so restless you could not sit still?

1. None of the time
2. A little of the time
3. Some of the time
4. Most of the time
5. All of the time

7. About how often did you feel depressed?

1. None of the time
2. A little of the time
3. Some of the time
4. Most of the time
5. All of the time

8. About how often did you feel that everything is an effort?

1. None of the time
2. A little of the time
3. Some of the time
4. Most of the time
5. All of the time

9. About how often did you feel so sad that nothing could cheer you up?

1. None of the time
2. A little of the time
3. Some of the time
4. Most of the time
5. All of the time

10. About how often did you feel worthless?

1. None of the time
2. A little of the time
3. Some of the time
4. Most of the time
5. All of the time

Submit

Eysenck Questionnaire

Please answer each question by clicking on 'Yes' or 'No' following the question. There are no right or wrong anwser, and no trick question. Work quickly and do not think too long about the exact meaning of questions.

1. Does your mood often go up and down? ○ Yes ○ No

2. Do you take much notice of what people think? ○ Yes ○ No

3. Are you a talkative person? ○ Yes ○ No

4. If you say you will do something, do you always keep your promise no matter how inconvenient it might be? ○ Yes ○ No

5. Do you ever feel 'just miserable' for no reason? ○ Yes ○ No

6. Would being in debt worry you? ○ Yes ○ No

7. Are you rather lively? ○ Yes ○ No

8. Were you ever greedy by helping yourself to more than your share of anything? ○ Yes ○ No

9. Are you an irritable person? ○ Yes ○ No

10. Would you take drugs which may have strange or dangerous effects?
- Yes
- No

11. Do you enjoy meeting new people?
- Yes
- No

12. Have you every blamed someone for doing something you knew was really your fault?
- Yes
- No

13. Are your feelings easily hurt?
- Yes
- No

14. Do you prefer to go your own way rather than act by the rules?
- Yes
- No

15. Can you usually let yourself go and enjoy yourself at a lively party?
- Yes
- No

16. Are all your habits good and desirable ones?
- Yes
- No

17. Do you often feel 'fed-up'?
- Yes
- No

18. Do good manners and cleanliness matter much to you?
- Yes
- No

19. Do you usually take the initiative in making new friends?
- Yes
- No

20. Have you ever taken anything (even a pin or button) that belonged to someone else?
- Yes
- No

21. Would you call yourself a nervous person?
- Yes
- No

22. Do you think marriage is old-fashioned and should be done away with?
- Yes
- No

23. Can you easily get some life into a rather dull party?
- Yes
- No

24. Have you ever broken or lost something belonging to someone else?
- Yes
- No

25. Are you a worrier?
- Yes
- No

26. Do you enjoy co-operating with others?
- Yes
- No

27. Do you tend to keep in the background on social occasions?
- Yes
- No

28. Does it worry you if you know there are mistakes in your work?
- Yes
- No

29. Have you ever said anything bad or nasty about anyone?
- Yes
- No

30. Would you call yourself tense or 'highly strung'?
- Yes
- No

31. Do you think people spend too much time safeguarding their future with savings and insurance?
- Yes
- No

32. Do you like mixing with people?
- Yes
- No

33. As a child were you every cheeky to your parents? ○ Yes ○ No

34. Do you worry too long after an embarrassing experience? ○ Yes ○ No

35. Do you try not to be rude to people? ○ Yes ○ No

36. Do you like plenty of bustle and excitement around you? ○ Yes ○ No

37. Have you ever cheated at a game? ○ Yes ○ No

38. Do you suffer from 'nerves'? ○ Yes ○ No

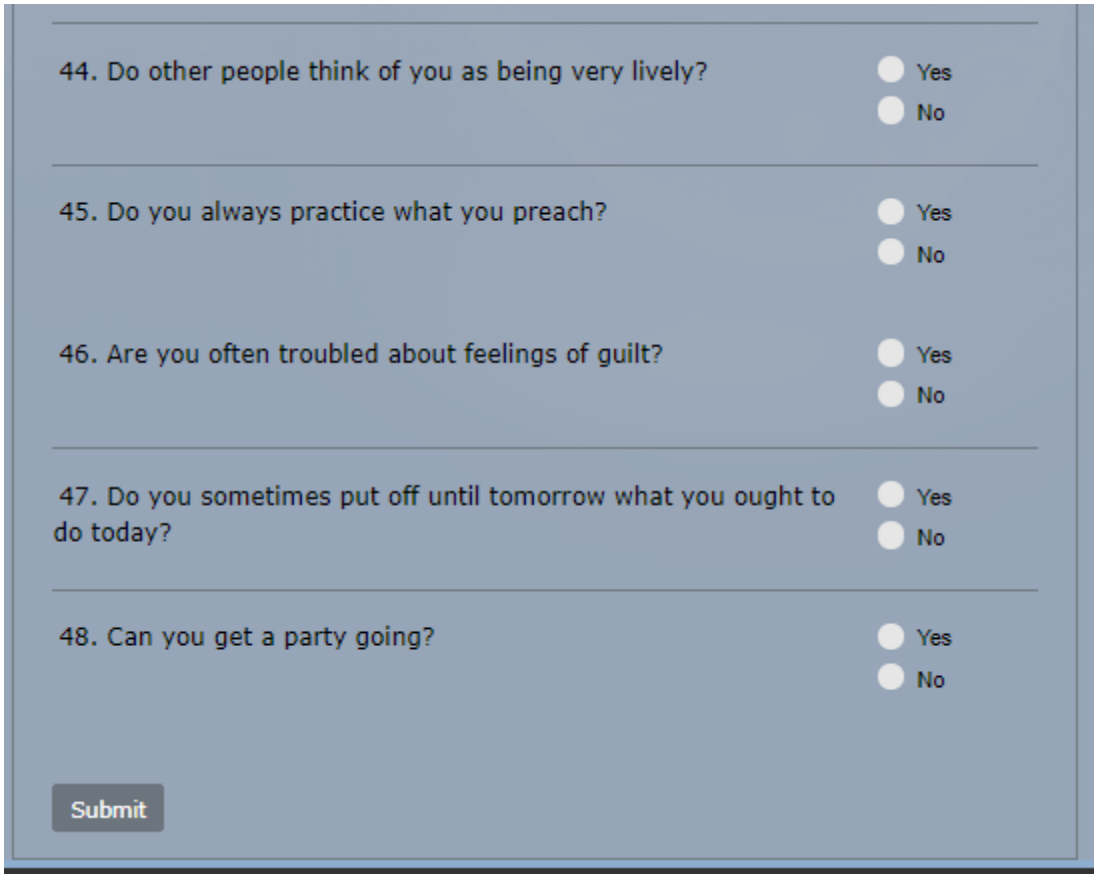
39. Would you like other people to be afraid of you? ○ Yes ○ No

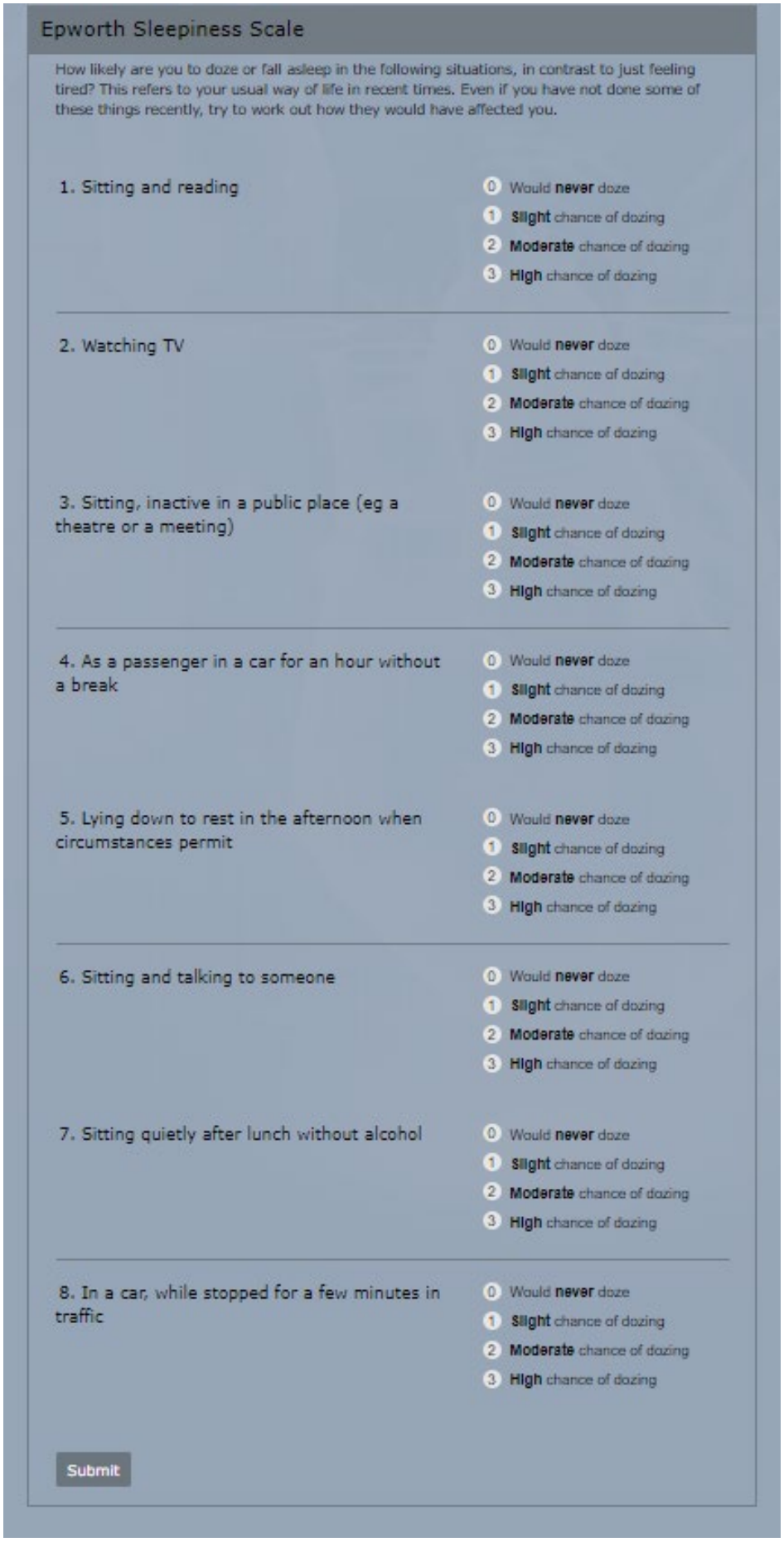
40. Have you ever taken advantage of someone? ○ Yes ○ No

41. Are you mostly quiet when you are with other people? ○ Yes ○ No

42. Do you often feel lonely? ○ Yes ○ No

43. Is it better to follow society's rules than go your own way? ○ Yes ○ No


44. Do other people think of you as being very lively?
Yes
No
45. Do you always practice what you preach?
Yes
No
46. Are you often troubled about feelings of guilt?
Yes
No
47. Do you sometimes put off until tomorrow what you ought to do today?
Yes
No
48. Can you get a party going?
Yes
No
Submit



Epworth Sleepiness Scale

How likely are you to doze or fall asleep in the following situations, in contrast to just feeling tired? This refers to your usual way of life in recent times. Even if you have not done some of these things recently, try to work out how they would have affected you.

1. Sitting and reading
   - 0 Would **never** doze
   - 1 **Slight** chance of dozing
   - 2 **Moderate** chance of dozing
   - 3 **High** chance of dozing

2. Watching TV
   - 0 Would **never** doze
   - 1 **Slight** chance of dozing
   - 2 **Moderate** chance of dozing
   - 3 **High** chance of dozing

3. Sitting, inactive in a public place (eg a theatre or a meeting)
   - 0 Would **never** doze
   - 1 **Slight** chance of dozing
   - 2 **Moderate** chance of dozing
   - 3 **High** chance of dozing

4. As a passenger in a car for an hour without a break
   - 0 Would **never** doze
   - 1 **Slight** chance of dozing
   - 2 **Moderate** chance of dozing
   - 3 **High** chance of dozing

5. Lying down to rest in the afternoon when circumstances permit
   - 0 Would **never** doze
   - 1 **Slight** chance of dozing
   - 2 **Moderate** chance of dozing
   - 3 **High** chance of dozing

6. Sitting and talking to someone
   - 0 Would **never** doze
   - 1 **Slight** chance of dozing
   - 2 **Moderate** chance of dozing
   - 3 **High** chance of dozing

7. Sitting quietly after lunch without alcohol
   - 0 Would **never** doze
   - 1 **Slight** chance of dozing
   - 2 **Moderate** chance of dozing
   - 3 **High** chance of dozing

8. In a car, while stopped for a few minutes in traffic
   - 0 Would **never** doze
   - 1 **Slight** chance of dozing
   - 2 **Moderate** chance of dozing
   - 3 **High** chance of dozing

Submit

DASS Scale

Please read each statement and click on a number 0, 1, 2 or 3 which indicates how much the statement applied to you *over the past week*. There are no right or wrong answers. Do not spend too much time on any statement.

The rating scale is as follows:

0 Did not apply to me at all

1 Applied to me to some degree, or some of the time

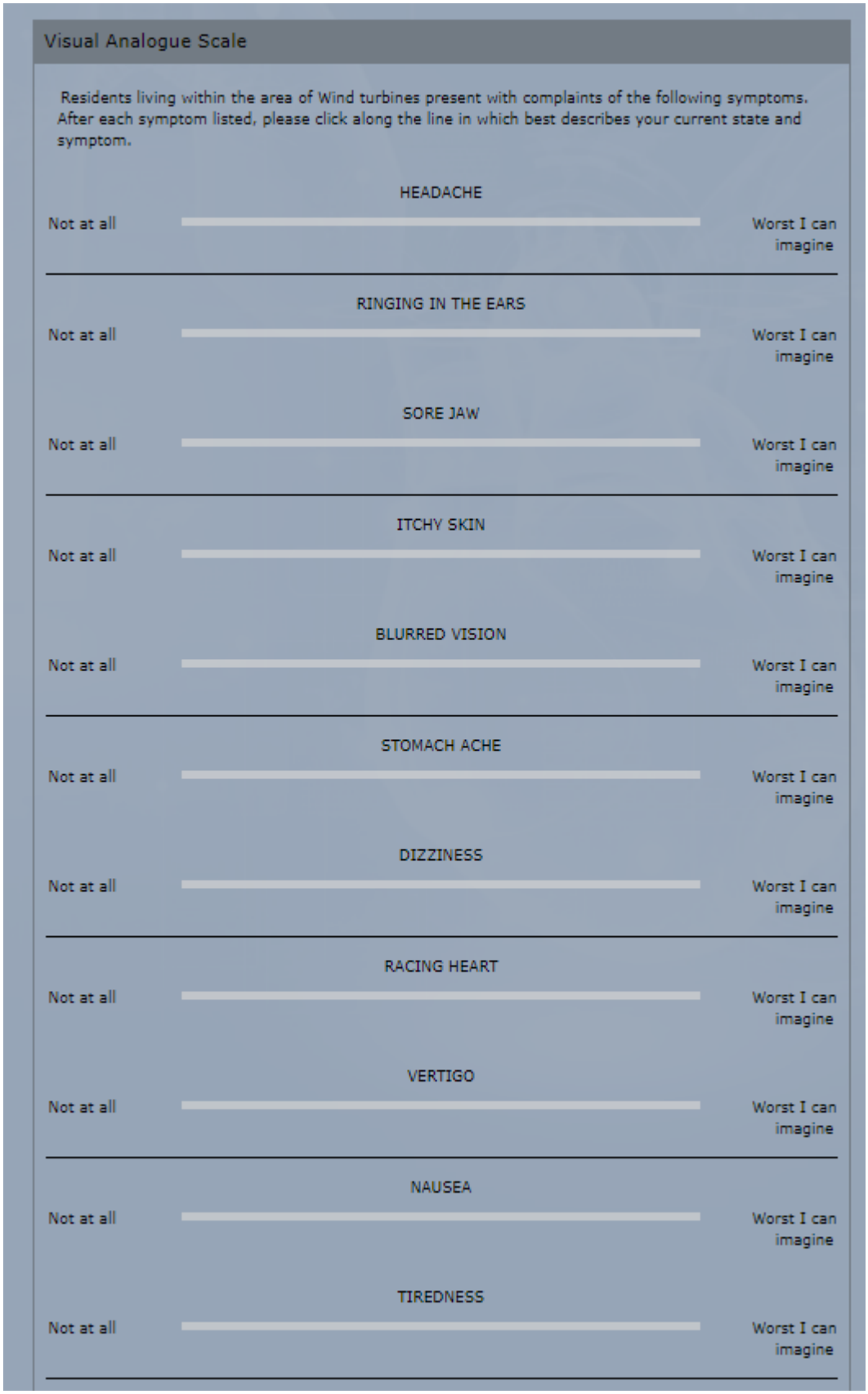
2 Applied to me to a considerable degree, or a good part of time

3 Applied to me very much, or most of the time

1. I found it hard to wind down	0 1 2 3
2. I was aware of dryness of my mouth	0 1 2 3
3. I couldn't seem to experience any positive feeling at all	0 1 2 3
4. I experienced breathing difficulty (eg, excessively rapid breathing, breathlessness in the absence of physical exertion)	0 1 2 3
5. I found it difficult to work up the initiative to do things	0 1 2 3
6. I tended to over-react to situations	0 1 2 3
7. I experienced trembling (eg, in the hands)	0 1 2 3
8. I felt that I was using a lot of nervous energy	0 1 2 3
9. I was worried about situations in which I might panic and make a fool of myself	0 1 2 3
10. I felt that I had nothing to look forward to	0 1 2 3

11. I found myself getting agitated	0 1 2 3
12. I found it difficult to relax	0 1 2 3
13. I felt down-hearted and blue	0 1 2 3
14. I was intolerant of anything that kept me from getting on with what I was doing	0 1 2 3
15. I felt I was close to panic	0 1 2 3
16. I was unable to become enthusiastic about anything	0 1 2 3
17. I felt I wasn't worth much as a person	0 1 2 3
18. I felt that I was rather touchy	0 1 2 3
19. I was aware of the action of my heart in the absence of physical exertion (eg, sense of heart rate increase, heart missing a beat)	0 1 2 3
20. I felt scared without any good reason	0 1 2 3
21. I felt that life was meaningless	0 1 2 3

Submit



Visual Analogue Scale

Residents living within the area of Wind turbines present with complaints of the following symptoms. After each symptom listed, please click along the line in which best describes your current state and symptom.

HEADACHE

Not at all — Worst I can imagine

RINGING IN THE EARS

Not at all — Worst I can imagine

SORE JAW

Not at all — Worst I can imagine

ITCHY SKIN

Not at all — Worst I can imagine

BLURRED VISION

Not at all — Worst I can imagine

STOMACH ACHE

Not at all — Worst I can imagine

DIZZINESS

Not at all — Worst I can imagine

RACING HEART

Not at all — Worst I can imagine

VERTIGO

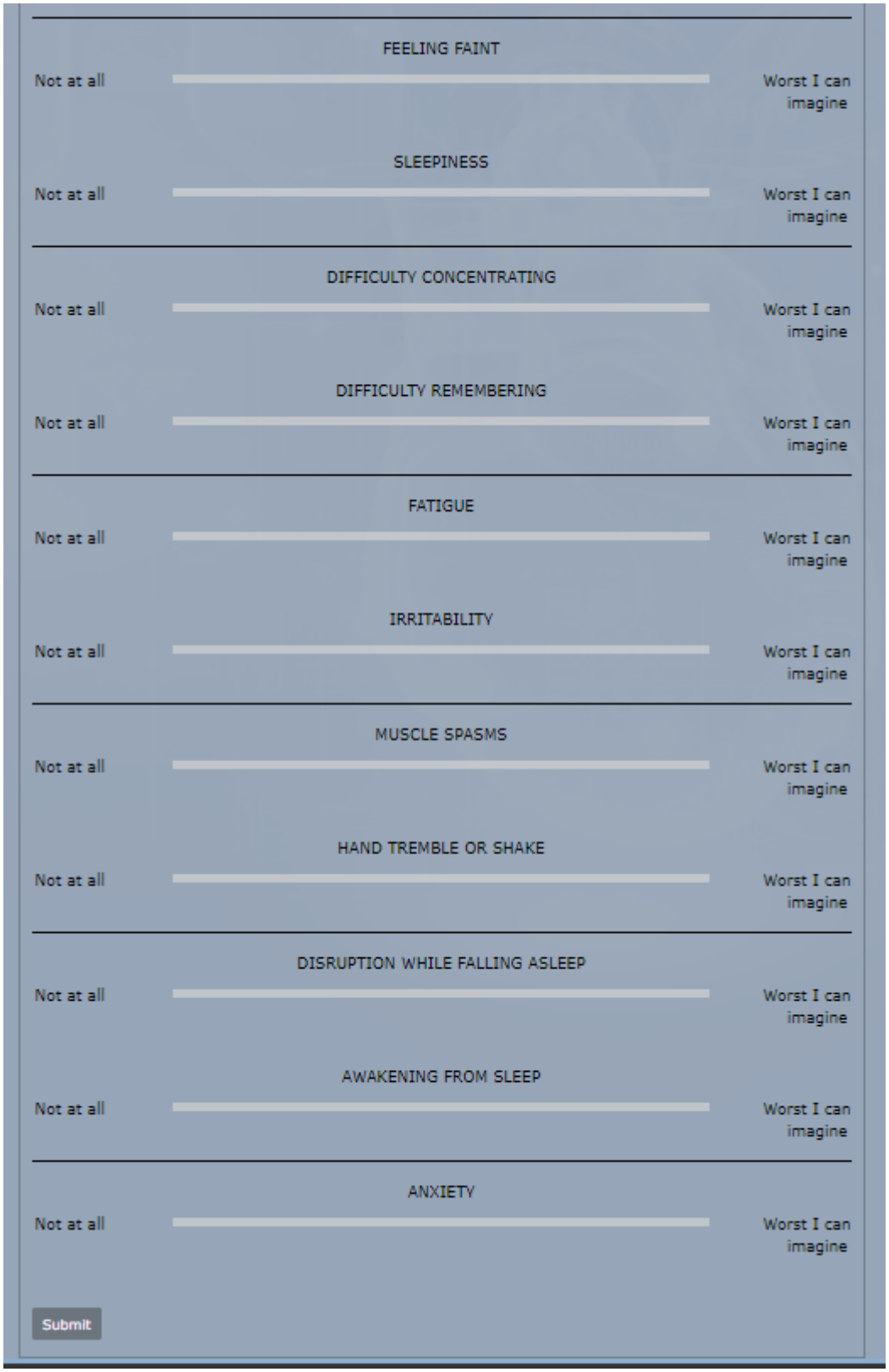
Not at all — Worst I can imagine

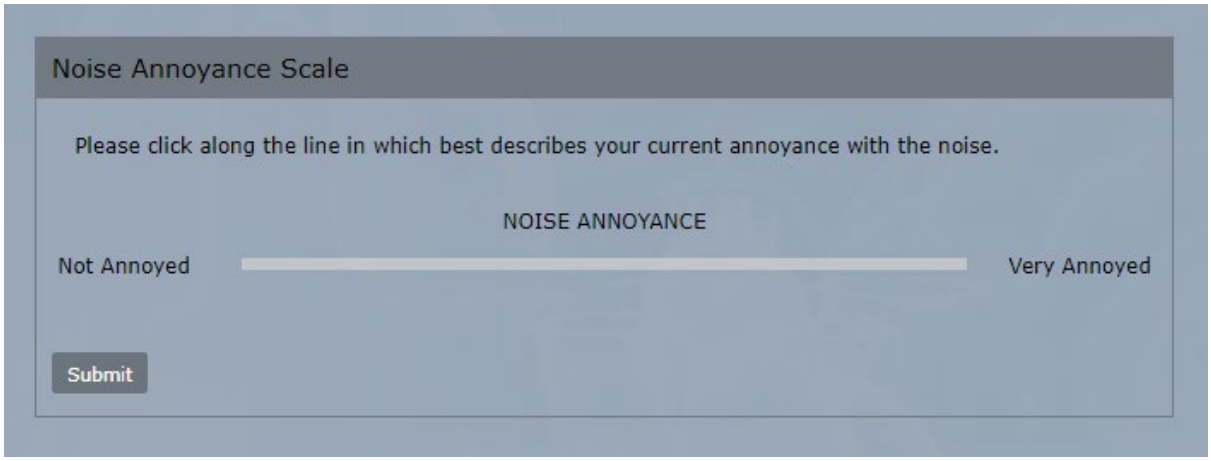
NAUSEA

Not at all — Worst I can imagine

TIREDNESS

Not at all — Worst I can imagine


FEELING FAINT
Not at all
Worst I can imagine
SLEEPINESS
Not at all
Worst I can imagine
DIFFICULTY CONCENTRATING
Not at all
Worst I can imagine
DIFFICULTY REMEMBERING
Not at all
Worst I can imagine
FATIGUE
Not at all
Worst I can imagine
IRRITABILITY
Not at all
Worst I can imagine
MUSCLE SPASMS
Not at all
Worst I can imagine
HAND TREMBLE OR SHAKE
Not at all
Worst I can imagine
DISRUPTION WHILE FALLING ASLEEP
Not at all
Worst I can imagine
AWAKENING FROM SLEEP
Not at all
Worst I can imagine
ANXIETY
Not at all
Worst I can imagine
Submit


Noise Annoyance Scale
Please click along the line in which best describes your current annoyance with the noise.
NOISE ANNOYANCE
Not Annoyed
Very Annoyed
Submit

C. Actiwatch and Sleep Diary

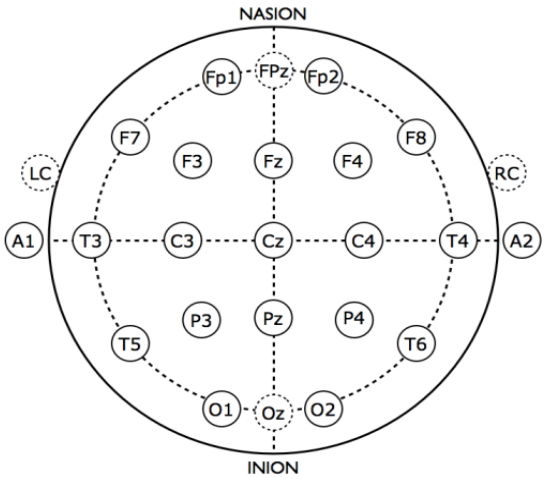
I. Actiwatch

II. Sleep Diary

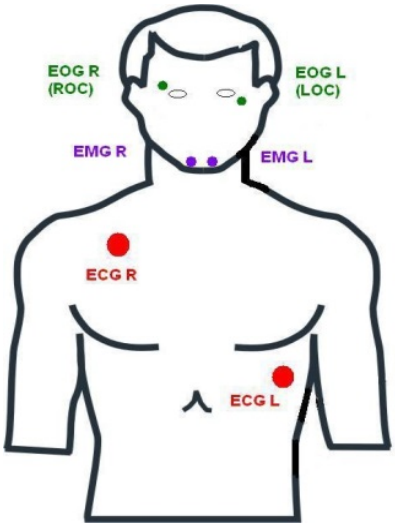
	Day 1
S1. Today's Date (dd/mm/yy)	
S2. Time	_____ h_____min
S3. What time did you go to bed?	_____ h_____min
S4. What time did you attempt to fall asleep?	_____ h_____min
S5. How long did it take you to fall asleep?	_____ h_____min
S6. What time did you finally	_____ h_____min
S7. How long did you sleep?	_____ h_____min
S8. How long did you stay in bed before getting up?	_____ h_____min
S9. How many times did you awaken? List each: approximately when you woke and for how long.	Number of times: When? _____ h_____min Length? _____ h_____min
S10. Did anything disturb your sleep? **[Yes / No] (check all that apply)**	☐ Noise ☐ Work Duties ☐ Thoughts on mind ☐ Toilet (#) ☐ Light ☐ Aches/Pains/Physical Discomfort ☐ Air Temperature ☐ Electronic Media (Phone/Email/SMS) ☐ Other: _____
S11. How would you rate your quality of sleep?	1= Best Sleep ever 2 3 4 5 = Neither best nor worst sleep 6 7 8 9 = Worst Sleep ever
S12. Please indicate the number which best describes how sleepy you have felt in the preceding 5 minutes	1 – extremely alert 2 – very alert 3 – alert 4 – rather alert 5 – neither alert nor sleepy 6 – some signs of sleepiness 7 – sleepy but no effort to stay awake 8 – sleepy but some effort to stay awake 9 – very sleepy, fighting sleep, great effort to stay awake
S13. Did you have any caffeine yesterday? [Yes / No] (indicate how much)	coffee_____ cups tea _____cups caffeinated soft drinks _____ cans caffeine pills _____(100mg) _____(200mg
S14. Did you have any alcohol yesterday? [Yes / No] (indicate how much)	beer _____ (375 ml glasses/bottles/cans) wine _____ (150 ml glasses) spirits _____ (30 ml nip)
S15. Did you exercise in the last 24 hours?	[Yes/No] How many times? When? _____ h_____min For how long? _____ h_____min How strenuous? (low, medium, high)
S16. Did you nap yesterday? [Yes / No] **How many times?** **List each: when the nap started and when it ended**	[Yes / No] Nap start _____ h_____min Nap end _____ h_____min
S17. Did you take sleeping pills to help you sleep?	[Yes/No] Was it ☐ Prescribed ☐ Over-the-counter Please provide details:
S18. How many times did you remove your activatch?	Number: Activatch removed at: _____ h_____min Put back on at: _____ h_____min
Comments	

D. Polysomnography (PSG) setup

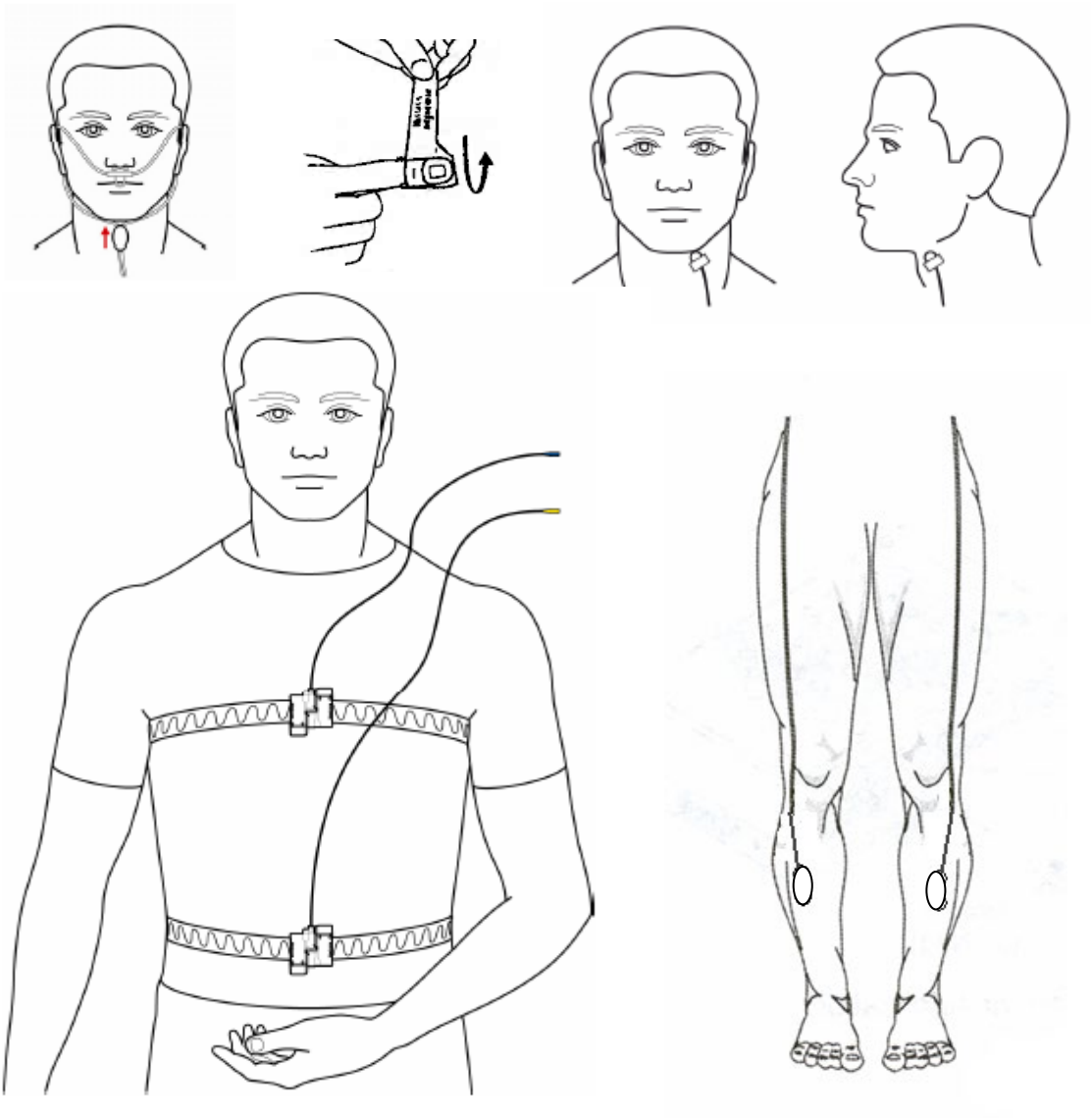
I. EEG setup



II. Additional ECG, EOG and EMG Chin electrode placements.

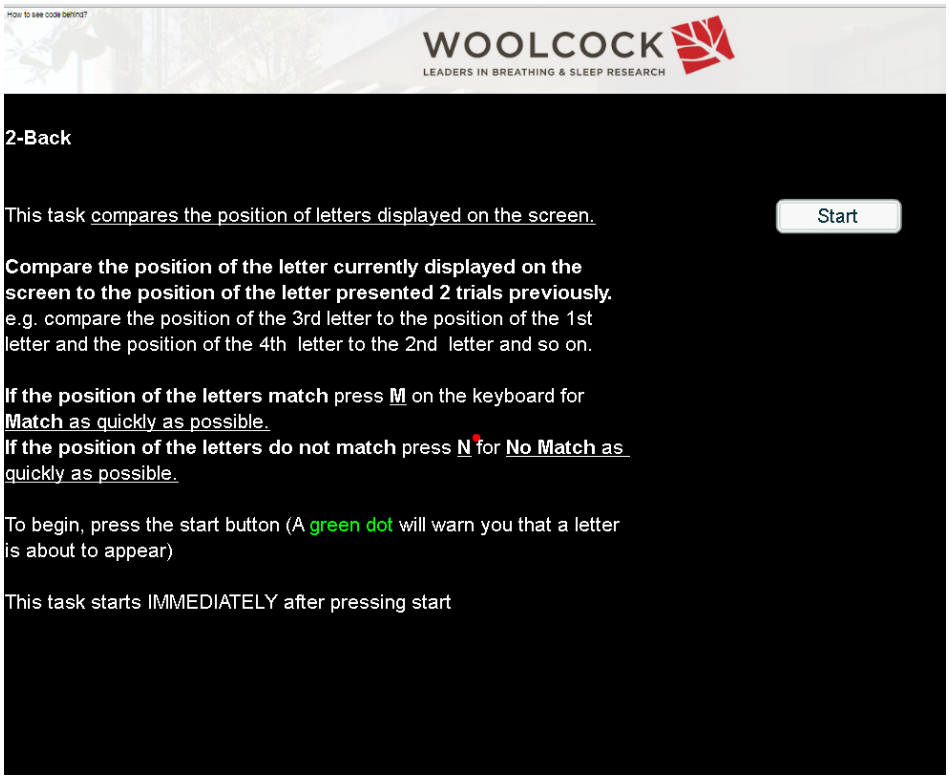


III. Additional PSG electrodes

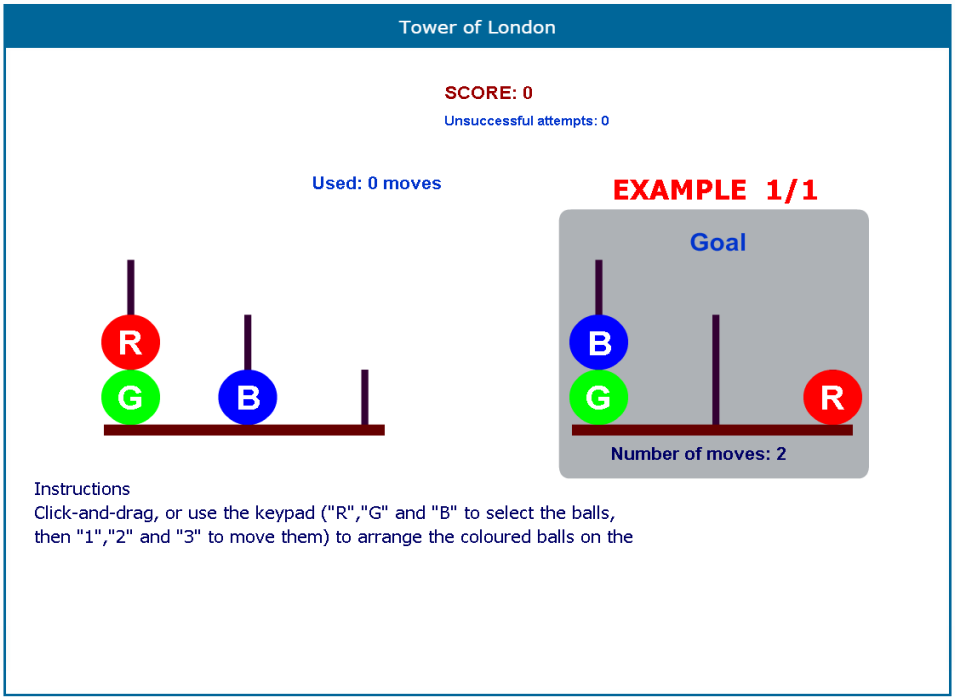


E. Neurocognitive Test

I. N-back (2-Back)



II. Tower of London



F. Cardiovascular and stress measures

SphygmaCor Xcel Device (Pulse Wave Velocity)

G. Summary table of major changes between 6 month study (Version 6.0, 2nd November 2018) and 1 month study (Version 7.0, 9th July 2019)

Protocol section	Version 6, 2nd November 2018	Version 7, 9th July 2019
2.Study objective (Pg 9)	Six months	One month
3.Experimental Design (Pg 9)	Non-metropolitan Sydney	Sydney
	Four speakers	Two speakers
6. Study interventions (Pg 11)	Audible and Infrasound microphone in bedroom	No audible microphone only infrasound in bedroom
7. Cardiovascular and Stress Measures (Pg 12)	Blood HbA1c and Hair Cortisol	Do not measure HbA1c or hair Cortisol
8. Home Screening (Pg 17)	Audiometry and collection of Actiwatch at home visit	Hearing assessed by over the telephone and Actiwatch sent and returned by Australia Post
8. Reimbursement (Pg 19)	$1000 at completion	$500 at completion
12. Neurootological Tests	In the home	At the Woolcock

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