*A Randomised Controlled Trial Comparing the Effects of Mindfulness and Exercise on Psychological and Physical Wellbeing in People with Cancer During and After Treatment.*

*Comparison of Mindfulness and Exercise During and After Cancer Treatment*

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*Project summary:*

Mindfulness (Gotnik et al, 2015; Rouleau et al, 2015) and exercise (Battaglini et al, 2014; Cormie et al, 2014) have been shown to have a positive impact on people with cancer’s health and wellbeing. This study aims to compare mindfulness with exercise in people who are having or have completed their treatment. Traditionally mindfulness and exercise studies have involved 2-5 hours per week of structured classes with expectations to do significant amounts of daily home practice (e.g. 45 minutes of formal mindfulness practice daily). This pilot study aims to test the feasibility of whether people during and after cancer treatment wish to, and are able to, attend a 6 weekly one hour group programme with daily homework of either 10 or 15 minutes of formal practice. We wish to investigate whether smaller ‘dose’ of exercise and/or mindfulness is feasible, acceptable and as effective in this population.

People attending St Georges Cancer Care the Glasson Centre (SGCCC) will be offered the opportunity to take part in 6 weeks of either exercise or mindfulness weekly sessions provided they are medically cleared as fit to participate. Once patients have given informed consent, they will be randomised to a 6 week group of mindfulness, exercise or to treatment as usual. Treatment as usual participants will be then randomised to either of the intervention groups following a six week wait period. Participants will complete a range of assessments on exercise, mindfulness and psychosocial symptoms at baseline, 3 and 6 weeks (end-treatment) and at 6-month follow-up. The study recruitment period will run over approximately 12 months to allow for group sizes large enough for statistical analysis. Our hypotheses are 1) Mindfulness and exercise have a positive effect on a range of psychosocial and physical symptoms compared to the waitlist group; 2) shorter classes and homework expectations are feasible for this population;3) that “lower dose” mindfulness and exercise groups will be as effective as traditional larger dose interventions; 4) that these positive effects will be maintained over 6 months follow-up and 5) that patients currently receiving cancer treatments will benefit from the mindfulness and/or exercise intervention to a similar extent as those post- cancer treatment.

*Background / justification for project:*

The lives of those with cancer are greatly affected by the diagnosis and treatment-related side effects of cancer (Fallowfield and Jenkins, 2015; Alfano and Rowland, 2006)). Treatment-related side effects include extensive decline in physical functioning, increased fatigue, adverse psychological and psychosocial functioning (Cleeland, 2010). Any of these effects may persist for several years after treatment completion (Stanton et al, 2015). Exercise for people both on active treatment and once treatment has finished (Cormie, et al, 2014) and mindfulness (Shennan et al, 2011) after treatment have been shown to help manage the above symptoms and improve patient’s wellbeing. Traditionally study interventions have been lengthy and required participants to commit several hours/week to attend classes and partake in home based practice. These interventions are time intensive for both participants and instructors. Mindfulness Intervention Studies (MIS) especially Mindfulness Based Stress Reduction (MBSR) studies typically require a significant time commitment (usually 2.5 hour class per week for 8 weeks, 45 minutes of daily practice and a day retreat) which may be difficult particularly for those patients who are unwell or are still undergoing treatment. Time spent in formal meditation practice has been shown to be significantly related to improvements in most facets of mindfulness and several measures of symptoms and well being. Increases in mindfulness have been shown to mediate the relationship between formal mindfulness practice and improvements in psychological functioning (Carmody and Baer, 2008). Jon Kabat- Zinn, 2013 (founder of MBSR) emphasises the importance of daily meditation and suggests that even short formal meditations (mindfulness) can be beneficial. To our knowledge the question of what amount of time and/or practice is required to be of benefit has not been explicitly explored.

We are investigating whether a smaller intervention ‘dose’, in structured class time (1 hour/week) and expectations for briefer home practice remains effective. We will be comparing two smaller ‘doses’ of formal mindfulness practice; under 10 minutes per day versus over 15 minutes per day of practice to see if this is effective, feasible and sustainable for this group

Similar to this, we are investigating whether a smaller exercise ‘dose’ of a one hour supervised class/week and additional home based exercises will be as effective as traditionally larger ‘dose’ exercise studies at reducing fatigue and improving patient’s quality of life.

We will include patients who are on active treatment or post treatment. There is a vast body of literature investigating the benefits exercise holds for patients on active treatment and those who have finished treatment (Battaglini et al, 2014). Exercise has been found to be a safe, appropriate and effective therapeutic option before, during and after cancer treatments for reducing symptoms and side effects (Mustain et al, 2016). In contrast there has been minimal research looking at on- treatment patients and mindfulness. A review by Shennan, C et al 2011 identified one on- treatment study. A recent New Zealand based study of participants undergoing chemotherapy identified increased symptom distress and reduced quality of life following mindfulness in the acute care setting (Reynolds et al, 2017). Limitations to their study (recruitment bias, no control group, rolling group format and facilitator bias) were identified as possible causal factors. Additionally the very nature of mindfulness requires participants to attend to and notice present-moment experience which in itself may be distressing. We plan to have closed groups, a control and mid intervention measurement to measure for increased distress.

*Aim:*

* To establish whether brief mindfulness or exercise practice is feasible and effective in improving a range of psychosocial outcomes and cancer and treatment related symptoms (e.g. decline in physical functioning, increased fatigue, pain, distress, sadness and enjoyment of life) in patients during 6 weeks of intervention and whether intervention effects are durable during follow-up.

*Primary outcomes:*

* To explore whether exercise and/or mindfulness is more effective in improving symptoms and psychosocial wellbeing in patients with cancer than treatment as usual control. This will be demonstrated by reduction in symptom measurements, both individual items (e.g. fatigue, pain, mood, enjoyment of life) and overall severity of/and impact of symptoms as measured by the MD Anderson Symptom inventory (MDASI) at 3 and 6 week. A 6 month comparison to control will not be available but we will be able to comment whether effects are maintained over time.
* To explore whether it is feasible, acceptable and effective to run smaller ‘dose’ groups, as demonstrated by good attendance rates or improved symptom measures on those able to attend.
* To explore whether brief mindfulness or exercise ‘dose’ is effective in improving patient’s symptoms and wellbeing.As measured by MDASI at 3 and 6 weeks when compared to treatment as usual.

*Secondary Outcomes*

* To assess the durability of treatment effects over 6 month follow-up taking into account the extent of continuing practice of mindfulness or exercise strategies.
* To explore whether patients who are on active treatment are able to benefit from mindfulness.
* To compare the effectiveness of two different sizes of ‘dose’ of mindfulness.

*Methodology:*

Study design / type:

* Randomised control trial with two intervention arms – mindfulness and exercise, and a treatment as usual control.
* Sample size: 20 per arm (exercise, mindfulness, waitlist). This is a pilot study testing the feasibility and acceptability of the treatment rather than power. Signals of effectiveness will inform the design of the larger randomised controlled trial.
* Sampling methods: Eligible patients attending St Georges Cancer Care the Glasson Centre will be invited to participate.
* Recruitment of 80 participants in one year is considered feasible given that each

Year, about 700 new patients attend St Georges Cancer Care the Glasson Centre,

approximately 140 are referred for psychological support and 140 currently attend exercise classes.

* A demographic questionnaire (Appendix A) will be administered at baseline (T1). Information collected includes age, gender, employment status, marital/living situation, ethnicity. Clinical data regarding diagnosis, date of diagnosis, and type of treatment – past and current will be obtained from the clinical notes held at St George’s Cancer Care Centre.
* Outcome measures: Measures will be repeated at baseline (T1), mid treatment -3 weeks (T2), end of treatment - 6 weeks (T3) and at follow-up 6 months (T4). Patients who are waitlisted will be assessed at randomisation baseline (T1W) and prior to starting treatment (T1W2). Outcome measures can be found in Appendix B

These include:

**MD Anderson Symptom Inventory (MDASI)** Cleeland, C. (2010) A multi-symptom patient reported outcome measure which includes highest frequency or severity symptoms reported by patients with different types of, and treatments, for cancer. Providing 19 individual symptoms scores (e.g. pain, fatigue, distress, enjoyment of life) and a total severity and a total interference of symptom scores. Numerous validation and reliability studies have shown the MADSI to be a reliable and valid measure ([www.mdanderson.org/symptom-research](http://www.mdanderson.org/symptom-research)).

**Five Facets of Mindfulness Questionnaire- Short Form (FFMQ-SF)** Bohlmeijer et al (2011) measures five distinct but related facets of mindfulness (observing, describing, acting with awareness, non-judging and non-reactivity). The measure is highly sensitive to change and is considered a reliable and valid instrument Bohlmeijer et al (2011).

**Exercise Measures:** Coopers6 minute walk test (Pollock, 2012), the 30-second chair stand test (Centers for Disease Control and Prevention, 2016) resting heart rate, and SOZO. The SOZO is a bio-impedance spectroscope which measures full body composition, including muscle mass and intra/extra cellular fluids. See Appendix B for a full description of these tests.

**Home-based practice:** A self- report measure regarding amount of weekly homework will be gathered. Appendix B.

It is anticipated that it will take participants between 10 and 20 minutes to complete the questionnaires at each time point. The exercise measures will take 10 minutes to complete.

Questionnaires will be administered on a tablet, however, pen and paper versions will be available for those who prefer this modality

Participants:

Inclusion criteria:

* Patients attending St Georges Cancer Care the Glasson Centre that are either on active treatment or attending for follow up appointments. Patients attending SGCCC who are above the age of 18, may have any type of cancer (the most common cancer presentations are breast and prostate) and are attending for either radiation therapy, chemotherapy or hormone treatment or for follow-up appointment. Participants who are able to complete questionnaires in English will be included.

Exclusion criteria:

* Exclusion criteria include patients with metastatic disease or those considered by their oncologist as not medically well enough to participate.

Procedure:

* Recruitment process: Patients attending our cancer care centre will be invited to participate and signs advertising the study will be posted on the walls. Patients will be invited to express interest at reception. Their details (name and contact number) will be collected at that time. An information sheet will be provided to those interested. A follow up phone call will be made to arrange an appointment with those wishing to participate to answer any questions, gain informed consent, check medical fitness, and to collect baseline data. Reasons for not wishing to participate will be also gathered by phone.
* Patients will then be randomised (T1 and T1W). Randomisation will be computer generated. Randomisation will be arranged in permuted blocks of eight.
* Those in the treatment as usual group will be further randomised after a 6 week waiting period into one of the two treatment groups and baseline assessment (T1W2) will be gathered.
* Those randomised to treatment will either be involved in a weekly exercise or mindfulness groups of one hour duration for a period of six weeks. Homework will be provided and a form for recording the amount of mindfulness or exercise undertaken between group sessions will be provided.
* See Appendix C for mindfulness and exercise group programme outlines.
* Follow-up assessments: Further assessments will be completed at 3 weeks (T2), 6 weeks (T3) and at 6 months (T4). Questionnaires will be completed electronically or paper form depending on preference.
* See Appendix D for study flow diagram.

Analysis plan:

* Data will be recorded in survey monkey and transferred to excel spread sheets. Data analysis assistance will be provided by our statistician Associate Professor Chris Frampton (Christchurch School of Medicine).
* Outcome measures will be compared among groups using linear mixed models which will include randomised treatments and in the case of active treatment, groups as a factor.

*Ethics:*

Participant safety:

* Medical clearance will be gained from patients oncologists prior to participation in the study. Participants will have the opportunity to contact study investigators if they have any concerns.

Informed consent:

* Information sheet provided and a meeting with a study investigator will be made for questions to be answered prior to consenting.

Confidentiality:

* Participants will be identified by study ID.

Data storage / protection:

* Information stored electronically in a de-identified form with study investigators only having password-protected access. Any de-identified hard copy information will be held in a locked filing cabinet.

*Project Management:*

Participating site:

* St Georges Cancer Care The Glasson Centre

Persons involved:

* Ginny Eggleston (Senior Clinical Psychologist) and Kathryn Taylor (Consultant Clinical Psychologist): facilitating and implementing the mindfulness programme, informing and consenting patients, data analysis, report/paper writing. Adiella Stewart (Radiation Therapist, BPhed (Hons), Mary Thompson (Physiotherapist), Julee Binns (Physiotherapist): facilitating and implementing the exercise programme, informing and consenting patients, assessing patients physical suitability for exercise ,data analysis, report/paper writing.

Administration/Reception Staff:

* First contact for study, arrange appointments for information/consent process. Involved as independent personnel in storing and issuing randomisation envelopes and other administrative tasks such as input of de-identified data.
* All staff working at St Georges Cancer Care the Glasson Centre: able to inform patients regarding the study and who to contact for further information.

*Data Ownership:*

Owned by St Georges Cancer Care the Glasson Centre

*Timetable:*

1. Planning, programme development, writing protocol, identifying suitable assessment measures, location approval and literature review (June 2016-Feb 2018).
2. Ethics and formal application process. (February 2018).
3. Setting up electronic and other requirements for study to proceed (i.e. Recording mindfulness formal practice, setting up survey monkey, establishing electronic access to mindfulness audio files, establish suitable exercise equipment/environment)(Feb-May 2018).
4. Recruitment and running intervention (May2018-May 2019).
5. Data analysis, report and paper writing. Submission to journals (June-Dec 2019).

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**APPENDIX A:**

**Demographic Questionnaire**

Comparison of Mindfulness and Exercise During and After Cancer Treatment: Demographic Questionnaire

**ID\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_**

1. Please tick which age bracket you are in:

|  |  |
| --- | --- |
| 18-25yrs |  |
| 26-35yrs |  |
| 36-45yrs |  |
| 46-55yrs |  |
| 56-65yrs |  |
| 66-75yrs |  |
| 76-85yrs |  |
| 86+yrs |  |

1. Please tick your gender

|  |  |
| --- | --- |
| Male |  |
| Female |  |
| Other (please state) |  |

1. What is your occupation? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. Please indicate which best describes your current employment status:

|  |  |
| --- | --- |
| Working full time |  |
| Working part time |  |
| Work on hold (during treatment/recovery) |  |
| Main child carer |  |
| Not in paid employment |  |
| Retired |  |

1. Please indicate which best describes your living situation:

|  |  |
| --- | --- |
| Married or Defacto |  |
| Single - Live with others |  |
| Single - Live alone |  |
| Other (please describe) |  |

1. What ethnicity do you identify as? Please tick as many as apply

|  |  |
| --- | --- |
| New Zealand European/Pakeha |  |
| New Zealand Maori |  |
| Other European |  |
| Pacific |  |
| Chinese |  |
| Indian |  |
| Other (please state) |  |

1. If you know your cancer diagnosis please include it here: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. If you know the date of your diagnosis please include it here:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. If you are having or have already had treatment for cancer please tick as many as apply the treatment or treatments listed below:

|  |  |
| --- | --- |
| Surgery |  |
| Chemotherapy |  |
| Radiotherapy |  |
| Other (please describe) |  |

1. Are you currently having treatment ?

|  |  |
| --- | --- |
| YES |  |
| NO |  |

1. If you know please indicate the treatment date and duration (approximate date or time period)

Eg Chemotherapy August 2013 weekly for 6 weeks.

|  |  |
| --- | --- |
| Surgery |  |
| Chemotherapy |  |
| Radiotherapy |  |
| Other (please describe) |  |

**APPENDIX B:**

**Outcome Measures**



Comparison of Mindfulness and Exercise During and After Cancer Treatment: Mindfulness Questionnaire

***5 facet questionnaire: short form (ffmq-sf)***

Below is a collection of statements about your everyday experience. Using the 1–5 scale below, please indicate, in the box to the right of each statement, how frequently or infrequently you have had each experience in the last month (or other agreed time period). Please answer according to what really reflects your experience rather than what you think your experience should be.

***never or not often sometimes true often very often very rarely true true sometimes not true true or always true***

***1 2 3 4 5***

|  |  |  |  |
| --- | --- | --- | --- |
| *1* | I’m good at finding the words to describe my feelings | *DS* |  |
| *2* | I can easily put my beliefs, opinions, and expectations into words | *DS* |  |
| *3* | I watch my feelings without getting carried away by them | *NR* |  |
| *4* | I tell myself that I shouldn’t be feeling the way I’m feeling | */NJ* |  |
| *5* | it’s hard for me to find the words to describe what I’m thinking | */DS* |  |
| *6* | I pay attention to physical experiences,  such as the wind in my hair or sun on my face | *OB* |  |
| *7* | I make judgments about whether my thoughts are good or bad. | */NJ* |  |
| *8* | I find it difficult to stay focused on what’s happening in the present moment | */AA* |  |
| *9* | when I have distressing thoughts or images,  I don’t let myself be carried away by them | *NR* |  |
| *10* | generally, I pay attention to sounds, such as clocks ticking,  birds chirping, or cars passing | *OB* |  |
| *11* | when I feel something in my body, it’s hard  for me to find the right words to describe it | */DS* |  |
| *12* | it seems I am “running on automatic”  without much awareness of what I’m doing | */AA* |  |
| *13* | when I have distressing thoughts or images, I feel calm soon after | *NR* |  |
| *14* | I tell myself I shouldn’t be thinking the way I’m thinking | */NJ* |  |
| *15* | I notice the smells and aromas of things | *OB* |  |
| *16* | even when I’m feeling terribly upset, I can find a way to put it into words | *DS* |  |
| *17* | I rush through activities without being really attentive to them | */AA* |  |
| *18* | usually when I have distressing thoughts or  images I can just notice them without reacting | *NR* |  |

***never or not often sometimes true often very often very rarely true true sometimes not true true or always true***

***1 2 3 4 5***

|  |  |  |  |
| --- | --- | --- | --- |
| *19* | I think some of my emotions are bad  or inappropriate and I shouldn’t feel them | */NJ* |  |
| *20* | I notice visual elements in art or nature, such as colors,  shapes, textures, or patterns of light and shadow | *OB* |  |
| *21* | when I have distressing thoughts or  images, I just notice them and let them go | *NR* |  |
| *22* | I do jobs or tasks automatically without being aware of what I’m doing | */AA* |  |
| *23* | I find myself doing things without paying attention | */AA* |  |
| *24* | I disapprove of myself when I have illogical ideas | */NJ* |  |

*correct scores for items preceded by a slash (/NJ, /AA, etc) by subtracting from 6*

***non react = ; observe = ; act aware = ; describe = ; non judge =***

Bohlmeijer, E., P. M. ten Klooster, et al. (2011). *"Psychometric properties of the five facet mindfulness questionnaire in depressed adults and development of a short form."* Assessment 18(3): 308-320. In recent years, there has been a growing interest in therapies that include the learning of mindfulness skills. The 39-item Five Facet Mindfulness Questionnaire (FFMQ) has been developed as a reliable and valid comprehensive instrument for assessing different aspects of mindfulness in community and student samples. In this study, the psychometric properties of the Dutch FFMQ were assessed in a sample of 376 adults with clinically relevant symptoms of depression and anxiety. Construct validity was examined with confirmatory factor analyses and by relating the FFMQ to measures of psychological symptoms, well-being, experiential avoidance, and the personality factors neuroticism and openness to experience. In addition, a 24-item short form of the FFMQ (FFMQ-SF) was developed and assessed in the same sample and cross-validated in an independent sample of patients with fibromyalgia. Confirmatory factor analyses showed acceptable model fit for a correlated five-factor structure of the FFMQ and good model fit for the structure of the FFMQ-SF. The replicability of the five-factor structure of the FFMQ-SF was confirmed in the fibromyalgia sample. Both instruments proved highly sensitive to change. It is concluded that both the FFMQ and the FFMQ-SF are reliable and valid instruments for use in adults with clinically relevant symptoms of depression and anxiety.

Comparison of Mindfulness and Exercise During and After Cancer Treatment: Exercise Group: Cooper’s 6min Walk Test

**Purpose:** To test aerobic fitness and endurance.

**Measures to be taken at baseline, 3 weeks, 6 weeks and 6 months from starting the intervention**

**Equipment:** Stop watch, flat walking track and marker cones.

**Directions:** Place markers at set intervals around the track to aid in measuring the completed distance. Participants run for 6 minutes, and the total distance covered is recorded. Participants will be encouraged to push themselves to maximize the distance covered.

**Instructions to the patient:**

1. Walk/run as far as you can in a 6 minute period.
2. Push yourself to walk as far as you can.

Comparison of Mindfulness and Exercise During and After Cancer Treatment: Exercise Group: the 30-Second Chair Stand Test

**Purpose:** To test leg strength and endurance

**Measures to be taken at baseline, 3 weeks, 6 weeks and 6 months from starting the intervention**

**Equipment:** Straight back or folding chair without arm rests (seat 17 inches/44 cm high), [stopwatch](http://www.topendsports.com/resources/stores.htm?node=28&cat=Stopwatches).

**Directions:** Place the chair against a wall, or otherwise stabilize it for safety. The subject sits in the middle of the seat, with their feet shoulder width apart, flat on the floor. The arms are to be crossed and held close to the chest. From the sitting position, the subject rises into the standing position and then sits down again. This is repeated for 30 seconds. Count the total number of time the patient comes to a full standing position in 30 seconds.

**APPENDIX C**

**Programme Outlines**

**Homework Sheets**

Comparison of Mindfulness and Exercise During and After Cancer Treatment: Mindfulness Group Class Content

**Week 1**

Grounding script

Introductions and ground rules

Introduction to mindfulness – raisin/mandarin experiment

Discussion of mindfulness “attitudes” of each week

Introduction to mindfulness script -Bodyscan

Mindfulness practice in class

Debrief

Setting the scene

Informal and formal practice

Workbook and Homework discussion

**Week 2**

Grounding script

Intentions Practice – pebble exercise (Trish Bartley pg 78)

Coming to the Breath

Introduction to new mindfulness script - Breath

Mindfulness practice in class

Debrief

Homework discussion

**Week 3**

Grounding script

Symptom management and mindfulness

The Pause

Introduction to new mindfulness script-Sound and Thoughts

Mindfulness practice in class

Debrief

Homework discussion

**Week 4**

Finding time for practice

Compassion for self and others

Introduction to new mindfulness script-Loving kindness

Mindfulness practice in class

Debrief

Homework discussion

**Week 5**

Difficult emotions and experiences – Breathing With

Introduction to new mindfulness script – Mountain meditation

Mindfulness practice in class

Debrief

Homework discussion

**Week 6**

Incorporating mindfulness into life

Introduction to new mindfulness script – Affectionate Body Scan

Mindfulness practice in class

Debrief

Review Intentions from second week

Reflections about the course

Homework discussion

Comparison of Mindfulness and Exercise During and After Cancer Treatment: Exercise Group Class content

**Week 1, 2 & 3**

**Warm up (10min):**

* x2 stair climbs
* Transition through 8 exercise stations doing 5 reps of each exercise with a light weight (0.5kg)

**Circuit stations (40min):**

* 8 stations, 30 seconds (sec)/station, 10 sec change over period. Complete 2x rounds of the 8 stations
* X2 stair climbs
* 8 stations, 30 seconds (sec)/station, 10 sec change over period. Complete 2x rounds of the 8 stations

**Cool down (10min):**

* Light Stretching

**Week 4, 5 & 6**

**Warm up (10min):**

* X3 stair climbs
* Transition through 8 exercise stations doing 5 reps of each exercise with a light weight (0.5kg)

**Circuit stations (40min):**

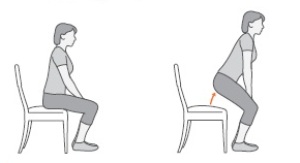
* 9 stations, 30 seconds (sec)/station, 10 sec change over period. Complete 2x rounds of the 8 stations
* X3 stair climbs
* 9 stations, 30 seconds (sec)/station, 10 sec change over period. Complete 2x rounds of the 8 stations

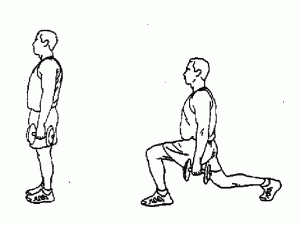
**Cool down (10min):**

* Light Stretching

Comparison of Mindfulness and Exercise During and After Cancer Treatment: Exercise Group Take Home Exercises

1. **20 minute light walk** (3x per week)

****

1. **Sit to stand exercise** (3x per week)
   * Sit and stand 15x in a row
   * 1 minute rest
   * Repeat 3 times
2. **Wall pushups** (3x per week)
   * Ensure feet are hip width apart
   * Hands on wall shoulder width apart
   * Stand 2 feet away from wall
   * Lower yourself slowly towards the wall and then push back off the wall
   * Do this 8 times
   * 1 minute rest
   * Repeat 3 times
3. **Lunges** (3x per week)
   * Take a large step forward
   * Ensure front knee is behind front foot
   * ****Dip hips down towards ground
   * Press back up
   * Do this 8 times (4x each leg)
   * 1 minute rest
   * Repeat 3 times

**Mindfulness Homework Sheet**

**NAME:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ID NUMBER:\_\_\_\_\_\_\_\_\_\_\_\_\_**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **DAY/DATE *Example*** | **M** | **T** | **W** | **TH** | **F** | | **SA** | **SU** | **Total time spent in week (minutes)** |
| *Formal Practice – Body Scan Audio* |  |  | * *Only ½ - 5mins* |  |  | |  |  | *45 mins* |
| *Informal Practice*  *Describe Practice/Time:* | *e.g.Shower 5 mins* | *Walking*  *20 mins* |  | *Cleaning teeth*  *3mins* | *Shower 5 mins* | |  | *Cleaning teeth*  *3mins* | *36 mins* |
| **Week 1: DATE** | **M** | **T** | **W** | **TH** | | **F** | **SA** | **SU** |  |
| Formal Practice – Body Scan Audio |  |  |  |  | |  |  |  |  |
| Informal Practice  Describe Practice/Time: |  |  |  |  | |  |  |  |  |
| **Week 2:** | **M** | **T** | **W** | **TH** | | **F** | **SA** | **SU** |  |
| Formal Practice – Breath Audio |  |  |  |  | |  |  |  |  |
| Informal Practice  Describe Practice/Time: |  |  |  |  | |  |  |  |  |
| **Week 3:** | **M** | **T** | **W** | **TH** | | **F** | **SA** | **SU** |  |
| Formal Practice – Sounds and thoughts Audio |  |  |  |  | |  |  |  |  |
| Informal Practice  Describe Practice/Time |  |  |  |  | |  |  |  |  |
| **Week 4:** | **M** | **T** | **W** | **TH** | | **F** | **SA** | **SU** |  |
| Formal Practice –Loving Kindness Audio |  |  |  |  | |  |  |  |  |
| Informal Practice  Describe Practice/Time |  |  |  |  | |  |  |  |  |
| **Week 5:** | **M** | **T** | **W** | **TH** | | **F** | **SA** | **SU** |  |
| Formal Practice – Affectionate Body Scan |  |  |  |  | |  |  |  |  |
| Informal Practice  Describe Practice/Time: |  |  |  |  | |  |  |  |  |

**Exercise Homework Sheet**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **DAY/DATE *Example*** | **M** | **T** | **W** | **TH** | **F** | | **SA** | **SU** | **Number of each activity** |
| *20 min walk (3x week)* |  |  |  |  |  | |  |  | *7* |
| *Sit to Stand (3x week)* |  |  |  |  |  | |  |  | *7* |
| *Wall Pushups (3x week)* |  |  |  |  |  | |  |  | *5* |
| *Lunges (3x week)* |  |  |  |  |  | |  |  | *4* |
| **Week 1: DATE** | **M** | **T** | **W** | **TH** | | **F** | **SA** | **SU** |  |
| 20 min walk (3x week) |  |  |  |  | |  |  |  |  |
| Sit to Stand (3x week) |  |  |  |  | |  |  |  |  |
| Wall Pushups (3x week) |  |  |  |  | |  |  |  |  |
| Lunges (3x week) |  |  |  |  | |  |  |  |  |
| **Week 2:** | **M** | **T** | **W** | **TH** | | **F** | **SA** | **SU** |  |
| 20 min walk (3x week) |  |  |  |  | |  |  |  |  |
| Sit to Stand (3x week) |  |  |  |  | |  |  |  |  |
| Wall Pushups (3x week) |  |  |  |  | |  |  |  |  |
| Lunges (3x week) |  |  |  |  | |  |  |  |  |
| **Week 3:** | **M** | **T** | **W** | **TH** | | **F** | **SA** | **SU** |  |
| 20 min walk (3x week) |  |  |  |  | |  |  |  |  |
| Sit to Stand (3x week) |  |  |  |  | |  |  |  |  |
| Wall Pushups (3x week) |  |  |  |  | |  |  |  |  |
| Lunges (3x week) |  |  |  |  | |  |  |  |  |
| **Week 4:** | **M** | **T** | **W** | **TH** | | **F** | **SA** | **SU** |  |
| 20 min walk (3x week) |  |  |  |  | |  |  |  |  |
| Sit to Stand (3x week) |  |  |  |  | |  |  |  |  |
| Wall Pushups (3x week) |  |  |  |  | |  |  |  |  |
| Lunges (3x week) |  |  |  |  | |  |  |  |  |
| **Week 5:** | **M** | **T** | **W** | **TH** | | **F** | **SA** | **SU** |  |
| 20 min walk (3x week) |  |  |  |  | |  |  |  |  |
| Sit to Stand (3x week) |  |  |  |  | |  |  |  |  |
| Wall Pushups (3x week) |  |  |  |  | |  |  |  |  |
| Lunges (3x week) |  |  |  |  | |  |  |  |  |

**NAME:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ID NUMBER:\_\_\_\_\_\_\_\_\_\_\_\_\_**

**APPENDIX D:**

**Protocol flow**

*Comparison of Mindfulness or Exercise During and After Cancer Treatment Study Flow*

Informed consent prior to Randomisation

**MDASI=**MD Anderson Symptom Inventory

**FFMQ SF**= Five Factor Mindfulness Questionnaire – Short form

**EM** = Exercise Measures (see protocol)

FMI=Freiburg Mindfulness Inventory

POM = Physiotherapy Outcome Measure

MD Anderson Symptom Inventory

**T4: 6 MONTH FOLLOW UP** Current exercise and mindfulness practice (3,6,6) **MDASI,** **FFMQ** and **EM**

**T4: 6 MONTH FOLLOW UP** current exercise and mindfulness practice (3,6,6) **MDASI**  and **FFMQ-SF**

Mindfulness Group

**T1:Pre Assessment**- Demographics, current exercise and mindfulness practice (pre-assessment), **MDASI,** **FFMQ-SF and EM**

**T1 W2Pre Assessment**- (post 6 week wait time) Current exercise and mindfulness practice, **MDASI**  **FFMQ** and **EM**

**T1W2Pre Assessment**- (post 6 week wait time) current exercise and mindfulness, **MDASI** and **FFMQ-SF**

**T2: 3 week** Current exercise and mindfulness practice (3,6,6) **MDASI,** **FFMQ** and **EM**

**T3: 6 WEEK POST ASSESSMENT** Current exercise and mindfulness practice(3,6,6) **MDASI,** **FFMQ-SF and mindfulness homework sheet**

**T2: 3 week** Current exercise and mindfulness practice (3,6,6) **MDASI** and **FFMQ-SF**

Exercise Group

Randomisation

Allocated to Waitlist.

Allocated to Exercise Group N= 6-10 per group

**T2: 3 week** Current exercise and mindfulness practice (3,6,6) **MDASI**, **FFMQ** and **EM**

**T4: 6 MONTH FOLLOW UP** Current exercise and mindfulness practice( 3,6,6) **MDASI** **FFMQ-SF** and **EM**

**T3:6 WEEK POST ASSESSMENT** : Current exercise and mindfulness practice (3,6,6), **MDASI,** **FFMQ-SF,** **EM and exercise homework sheet**

**T4: 6 MONTH FOLLOW UP** Current exercise and mindfulness practice (3,6,6) **MDASI** and **FFMQ-SF**

**T3: 6 WEEK POST ASSESSMENT** : Current exercise and mindfulness practice (3,6,6), **MDASI,** **FFMQ-SF and EGM and mindfulness homework sheet**

**T2: 3 week** Current exercise and mindfulness practice (3,6,6) **MDASI** and **FFMQ-SF**

Allocated to Mindfulness Group N= 6-10 per group

**T3: 6 WEEK POST ASSESSMENT** Current exercise and mindfulness practice (3,6,6) **MDASI,** **FFMQ-SF** and **EM and exercise homework sheet**