Title: Mindfulness-based intervention for teenagers with cancer: Rationale and protocol development for a randomized, wait-list clinical trial.

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Abstract

Background Individuals living with cancer must learn to face not only the physical symptoms of their condition, but also the anxiety and uncertainty related to the progression of the disease, the anticipation of physical and emotional pain related to illness and treatment, the significant changes implied in living with cancer, as well as the fear of recurrence after remission. Mindfulness-based meditation constitutes a promising option to alleviate these manifestations.

Purpose This article presents the rationale and protocol development for a research project aimed at evaluating the effects of a mindfulness-based meditation intervention on quality of life, sleep and mood in adolescents with cancer compared to a control group.

Methods/Design A prospective, longitudinal experimental design involving three time points (baseline, post-intervention and follow-up) and two groups (experimental and control) was developed for this project. Participants will be assigned randomly to either group. Eligible participants are adolescents aged 11 to 18 years with a diagnosis of cancer, with no specific selection/exclusion based on type, stage or trajectory of cancer. A final sample size of 28 participants is targeted. Adolescents in the experimental group will be completing the mindfulness meditation intervention, taught by two trained therapists. The intervention will comprise of eight weekly sessions, lasting 90 minutes each. Once the follow-up assessment completed by the experimental group, wait-list controls will be offered to complete the mindfulness-based program. Intra-group analyses will serve to evaluate the impact of the mindfulness-based meditation intervention on quality of life, sleep and mood pre-post intervention, as well as follow-up. Analyses will also be used to carry out inter-group comparisons between the experimental group and the wait-list controls.
Limitations Voluntary participation, risk of attrition and the small sample size are potential limitations of this project.

Conclusions In spite of possible limitations, this project will be one among very few aimed at improving quality of life, sleep and mood in adolescents living with cancer, will evaluate the potential benefits of such a practice on both psychological and physical health of youth with cancer and help in creating mindfulness-based intervention programs, in order to provide the necessary psychological help to adolescents living with cancer.

Keywords

Mindfulness-based meditation
Pediatric Cancer
Quality of life
Mood
Sleep
Adolescence
Health psychology
Introduction

News of a cancer diagnosis has been said to induce the greatest psychological distress among all prognoses and illnesses [1]. Thus, it often elicits a strong emotional reaction in teenagers and their parents [2]. Individuals living with cancer must learn to face not only the physical symptoms of their condition, but also the anxiety and uncertainty related to the progression of the disease, the anticipation of physical and emotional pain related to illness and treatment, the significant changes implied in living with cancer (ex. hair loss, frequent visits at the hospital), as well as the fear of recurrence after remission [3, 4]. To address these challenges, various psychosocial approaches have been developed, including mind-body therapies. Mindfulness-based meditation, initially developed to improve quality of life in patients suffering from chronic illnesses, constitutes a promising option [5]. The goal of this article is to describe the development, rationale and first phase of a pilot-study evaluating the effects of a mindfulness-based intervention on quality of life, mood and sleep for teenagers with cancer.

The Mindfulness-Based Stress Reduction program

Mindfulness can be defined as the process by which we “[...examine] who we are, with questioning our view of the world and our place in it, and [...cultivate] some appreciation for the fullness of each moment we are alive. Most of all, it has to do with being in touch.” [6]. It lies at the center of the Minfulness-Based Stress Reduction program (MBSR) developed by Kabat-Zinn and colleagues [5]. Specifically, mindfulness meditation allows us to “[...pay] attention in a particular way: on purpose, in the present moment, and nonjudgmentally.”
Kabat-Zinn and colleagues [5] initially developed the MBSR program to address, explore and decrease emotional and physical pain in patients suffering from a chronic illness, while observing the connection between the mind and the body. Anxiety and worry fueled by past and future events are hypothesized to ruin both physical and psychological health by increasing levels of stress. Thus, the MBSR program aims to bring focus to the present moment [7]. Its main goal is to bring awareness to different manifestations of stress, in order to detect first signs of anxiety and to act voluntarily and willingly to correct usual patterns of response. Thus, anxiety and depressive affect that often accompany stress can be targeted quickly, in order to achieve general well-being and peace of mind [8].

**Background and rationale**

As previously mentioned, individuals living with cancer are at risk for significant psychological distress [3, 4, 9]. Approximately 20 to 30% of individuals with cancer manifest depressive symptoms of clinical significance [10]. Moreover, chronic physical symptoms, such as sleep disorders and fatigue, tend to appear consequently to cancer treatments; approximately 85 percent of individuals with cancer suffer from sleep disorders [11, 12].

Recent studies have shown a positive impact of MBSR on psychological health in individuals with cancer. Specifically, a recent meta-analysis has indicated moderate effect-sizes of mindfulness meditation on stress, anxiety, depression, quality of life, sleep and fatigue related to cancer, highlighting the predominant role this practice can play in the individual’s psycho-social adaptation [9]. Research has also shown both immediate and one-year post-intervention positive impacts of the practice on stress, quality of life and mood in the same population [11, 13, 14]. Furthermore, the group setting in which MBSR takes place has been shown to decrease isolation
and loneliness often observed in the context of cancer, therefore promoting better relationships and stronger social support, which, in turn, may explain improvements in mood and quality of life [15].

Altogether, authors have concluded that mindfulness meditation has beneficial effects on physical and psychological symptoms among adults with different chronic illnesses, and could hence be a key tool in the treatment of these conditions [16, 17]. Emerging research in pediatrics is suggesting similar effects in children and adolescents [18-21]. The few studies that have examined its effects on youth with chronic illnesses tend to suggest that mindfulness meditation acts similarly by decreasing physical and emotional pain [22].

**Research Aim and Hypotheses**

This article presents the rationale and protocol development for a research project aimed at evaluating the effects of a mindfulness-based meditation intervention on quality of life, sleep and mood in adolescents with cancer compared to a control group. In light of data available on adult populations and emerging from research in youth, three hypotheses are formulated: 1) mindfulness meditation will have beneficial effects on the mood of adolescents completing this practice; 2) mindfulness meditation will have beneficial effects on quality of life of the participants; and 3) mindfulness meditation will have beneficial effects on sleep quality of the participants.

Specifically, significant improvements are expected to be observed in quality of life, mood and sleep between pre-intervention and post-intervention measures in the experimental group. These effects should be sustained six-months post-intervention.
Methods

Design

A prospective, longitudinal experimental design involving three time points (baseline, post-intervention and follow-up) and two groups (experimental and control) was developed for this project. Participants will be assigned randomly to either the experimental or control group. The longitudinal design will allow the evaluation of the short and long term effects of the intervention. Figure 1 illustrates the overall design and subject flow for this project. All study procedures and consent forms received IRB approval.

Figure 1. Design and Subject flow

Participants

Based on prior studies testing cognitive-behavioural interventions in adolescents with cancer, eligible participants are adolescents aged 11 to 18 years with a diagnosis of cancer [23-25]. In keeping with previous research, there will be no specific selection/exclusion based on type, stage or trajectory of cancer [11, 26-28]. The intervention will be conducted in French. Therefore, participants are required to speak and understand the language. They must be willing to participate in an eight-week mindfulness meditation program and be available to complete the measures six months after the intervention. They must not have a diagnosis of severe mental illness. A final sample size of 28 participants is targeted. Taking into consideration attrition rates from prior research (20-30%), an additional 12 participants will be recruited [2, 29-31]. Participants will be randomly assigned to the experimental or control group, and immediately
given a participant ID for confidentiality and anonymization purposes. Twenty adolescents will be completing the mindfulness meditation intervention, which will be taught by two trained therapists (doctoral clinical psychology student and psychiatrist). The intervention will comprise of eight weekly sessions, lasting 90 minutes each.

**Recruitment**

Recruitment for this project has started in September 2012, and is performed in the oncology centre of a university-affiliated pediatric hospital in a large urban area. Physicians and nurses have been invited to discuss the project with their patients when they visit the hospital for their regularly scheduled appointments. In addition, research nurses have screened hospital records to identify patients who qualify for this study (i.e. teenagers with cancer and no ongoing or lifetime severe psychopathology, such as schizophrenia, psychosis, delusional disorders or organic mental disorders), and introduced to them the project. Posters and brochures have been posted and available throughout the oncology wing of the hospital. Supplemental advertisement has been sent through the province-wide Association for Children with Cancer’s monthly newsletter, via mass emailing.

**Screening procedures, consent to participate and enrollment**

One of two screening and enrollment procedures has been applied, depending on the modality of first contact with potential candidates for the project. When contacted by telephone by teenagers having heard of the project and interested in participating, researchers summarize the study, and a meeting is scheduled to complete screening procedures, sign the consent forms and complete pre-intervention measures. When participants are recruited directly on site, screening, consent, enrollment and pre-intervention measures are completed immediately. Participants are informed
of the possibility of a delay (a few weeks up to a few months) before starting the intervention, as participants continue to be recruited. Intervention will begin either when: 1) 20 participants are selected to be in the experimental group; or 2) 10 participants are selected to be in the experimental group (thus implying that two experimental groups of 10 participants will be run), depending on recruitment speed and efficiency.

**Wait-list**

The use of a wait-list control condition has been compelling in past studies on MBSR and cancer to test for the effectiveness of the intervention without compromising recruitment, while favoring retention of participants who will later benefit from the intervention [31, 32]. Once the follow-up assessment has been completed with the experimental group, wait-list controls will be offered to complete the mindfulness-based program. The data collected on these participants through the second round of intervention will also be analyzed to test the mindfulness-based intervention.

**Experimental group**

The present mindfulness-based meditation intervention is inspired by protocols designed at the Centre de consultation psychologique spécialisé of the Université Catholique de Louvain (Belgium) [33], as well as by Biegel and colleagues [34]. The intervention will be led by two trained therapists (psychologist and psychiatrist), alternating roles (leader vs. co-leader) at each session, leading a total of four sessions each. In accordance with the initial MBSR program designed by Kabat-Zinn and colleagues [5], the mindfulness-based intervention will last eight weeks, the group meeting once a week and each session lasting 90 minutes. Based on previously cited protocols designed for youth, no silent retreat will be included in this intervention.
Mindfulness-based intervention protocol

Week 1
The mindfulness intervention will begin with an overview of class rules and the eight-week program. Participants will present each other in dyads, then to the whole group. They will also be asked to write down expectations and intentions in regards to the intervention (these will be collected by the therapists and handed back to all participants at the last session). An introduction to mindful eating with a cranberry tasting exercise will take place. Home practice for this session will include completing mindful tasks during the week and a “thinking outside the box” exercise. A minimal practice of 30 minutes each week, followed by an entry in their weekly meditation journal will be suggested to participants.

Week 2
Participants will be guided through a body scan meditation. An introduction to the different components of emotions (i.e. thoughts, physical sensations, behaviour) and stress, as well as their effect on the body and mind will be discussed. An outstretched arms meditation will be completed, in order to practice mindfulness through pain. Home practice will include familiarization with the body scan and cultivating mindfulness of the body.

Week 3
Participants will be guided through a breathing meditation and will be introduced to sitting meditation. Mindful movements will also be introduced, through gentle yoga-like poses inspired by readings from “Mindful Movements : Ten Exercises for Well-Being”[35]. Home practice will include sitting meditation and mindful breathing in the context of pleasant and unpleasant events.
Week 4
Participants will be guided through a breathing meditation. Concepts of acceptance of thoughts, emotions and bodily sensations will be discussed. In dyads, participants will be asked to exchange about suffering. During this activity, they will be asked to stop periodically and do a mindful check-in of how they are feeling while discussing a difficult topic. Home practice will include sitting meditation and the reading of Rumi’s “The Guest House” poem.

Week 5
Participants will be guided through a breathing meditation, with a special focus on thoughts and judgements. Mindful senses will then be explored, mainly through mindful touching and breathing. Participants will complete an inhibition activity and will be asked to reflect on our natural propensity to have spontaneous negative thoughts and judgements and discussing how we can come to inhibit such thoughts. Home practice will include meditation on thoughts and judgements.

Week 6
Participants will be guided through a heartfulness meditation, with a special focus on self-care and sending compassion to others. A group discussion on the topic of self-care vs. selfishness will take place. The concept of acceptance will also be explored. The session will end with a short sitting meditation with an emphasis on acceptance. Home practice will include heartfulness meditation and mindful activities that provide self-care.

Week 7
Participants will be guided through the mountain meditation. In dyads, participants will be asked to recall an autobiographical memory and identify how this memory reflects their personal
values. A group discussion on personal and life values will then take place. Participants will be asked to reflect whether mindfulness can be considered as a value or a tool in living in accordance with our personal values. Home practice will include any type of meditation practiced in the previous weeks, as well as a reflecting on the importance of being mindful while acting accordingly to personal values.

**Week 8**

Participants will have the choice of the type (sitting vs. lying down) of meditation and special focus they want to bring to the practice. Intentions set at the first session will be redistributed to all participants. Participants will be given the opportunity to exchange about the intervention and give comments and feedback to the therapists. A giant puzzle activity will take place, in which participants will be asked to write on each piece personal benefits and/or disadvantages of the intervention and their meditation practice. The session will end with the distribution of a pebble stone to each participant as a reminder of their experience.

**Measures**

**Assessment time-points**

Measures will be completed by all participants (i.e., experimental and control group) at three moments in time: 1) baseline, after the screening interview, consent forms are signed and enrollment is confirmed; 2) immediately post-intervention, at the end of the eighth week session, and; 3) six months follow-up, when questionnaires will be sent out by mail. At each time period, participants will fill out the questionnaire package, taking approximately 60 minutes to complete. There will be time allocated at the first and last sessions to complete questionnaires on site. After the third assessment period, once the last questionnaire package has been sent back to the
research team, a 10-dollar iTunes gift cards will be mailed to each participant to thank him/her for his/her participation. All measures and corresponding assessment time-points are illustrated in Figure 2.

**Primary outcome measures**

*Beck Youth Inventories*™ – *Depression and anxiety scales* [36]. This measure will be used to evaluate symptoms of depression and anxiety. Each scale comprises 20 items, for which participants are asked to indicate on a Likert-type scale ranging from 0 – “never” to 3 – “always” how frequently each statement applied to them in the past two weeks. Both scales have presented excellent internal consistency ($\alpha > 0.84$) and good reliability ($r > 0.73$) for adolescent populations [37]. For the purposes of this project, a validated French version will be used [38].

*Positive and Negative Affect Schedule – Child (PANAS-C)* [39]. This measure is used to evaluate the presence and fluctuations in positive and negative emotions. The questionnaire comprises 20 items, for which participants are asked to answer on a Likert-type scale ranging from 1 – “not much or not at all” and 5 – “a lot”, whether the described emotion matches what they have felt like in the past few weeks. This measure presents excellent results in terms of internal consistency ($\alpha$ ranging from 0.91 to 0.92) and good reliability for adolescent populations [40]. A French version has been validated, and will be used for this project [41].

*Pediatric Cancer Quality of Life Inventory* [42]. This measure is used to evaluate quality of life in children and adolescents with cancer. The questionnaire comprises 27 items for which participants are asked to indicate on a Likert-type scale ranging from 0 – “never” to 4 – “almost always” how much each symptom has been problematic in the past month. The measure has good to excellent psychometric properties in terms of construct validity, reliability, internal
consistency ($\alpha = 0.91-0.92$) and clinical validity [42]. A French version of this questionnaire is available and will be used for this project [43].

*Pittsburgh Sleep Quality Index* [44]. This measure evaluates sleeping habits in the past month. The questionnaire comprises 11 items, and presents good psychometric properties in terms of internal consistency ($\alpha = 0.83$), test-retest reliability ($r = 0.85$) and convergent validity [44]. This measure is commonly used with adolescents and is validated in French [45-47].

**Process measure**

*Children and Adolescent Mindfulness Measure* [48]. This measure is used to evaluate mindfulness in children and adolescents. The questionnaire comprises 25 items, for which participants are asked to indicate on a Likert-type scale ranging from 0 – “never true” to 4 – “always true” how often each item is true for them. This measure is included in the project in order to assess the extent to which adolescents become more mindful as they receive the intervention, as well as to control for existing differences between participants in their natural tendency to embody mindfulness concepts. The measure presents good internal consistency ($\alpha = 0.87$), as well as good convergent validity, and is available in French [48].

In addition, in-house social support analog scales presently in development will be administered, in order to evaluate if any improvements on quality of life, mood and sleep can be linked to social support and the overall social nature of the intervention.

**Figure 2. Measures and Assessment Time-Points**
**Planned statistical analyses**

Primary hypotheses will first be tested using the Friedman test, which constitutes the non-parametric alternative to analyses of variance and will allow comparison of data at each time-point [49]. These intra-group analyses will serve to evaluate the impact of the mindfulness-based meditation intervention on quality of life, sleep and mood pre-post intervention, as well as follow-up. The Mann-Whitney U test with independent samples will also be used to carry out inter-group comparisons between the experimental group and the wait-list controls. The Friedman test will also be conducted with the data collected from the second experimental group once participants go through the intervention.

**Statistical power**

Effect sizes will first be calculated using the Wilcoxon test, in order to evaluate the pre-post effect of the intervention. Cohen’s $d$ will also be calculated in order to evaluate the effect of the intervention between groups. Based on the previous literature on MBSR and oncology, small effect sizes are usually found [31]. Given the pilot-testing nature of this study, it may be that we will not detect large group differences. In this perspective, clinical significance and cues of intervention success will be evaluated based on individual courses and established cutpoints for each primary outcome variable. Participant journals may also be taken into consideration for qualitative information regarding the intervention.

**Quality control**

Therapists will keep a weekly log of each session, including attendance, level of participation, activities that were preferred, not correctly understood or not appreciated by participants. All
participants will be encouraged to keep a mindfulness diary, in which information such as impressions, home practice, formal and informal meditations, time spent meditating in the past week, hospital visits, sick days and general wellbeing could be logged in. Videotaping of each session will ensure intervention validity, as both therapists will receive an hour of clinical supervision for each session, provided by two duly trained MBSR and mindfulness-based cognitive therapy (MBCT) psychologists from the Centre de consultation psychologique spécialisé of the Université Catholique de Louvain (Belgium) who will review the videos.

Potential limitations

Voluntary participation to this project constitutes a potential limitation, as it could imply that adolescents and their parents who take part are individuals who are either: 1) genuinely interested in the concept of mindfulness and in the action of meditating, thus potentially displaying a higher level of mindfulness than the general population of adolescents with cancer; or 2) potentially healthier and in better shape than those who chose not to participate, as meditation can be demanding. In both cases, these potential confounds will likely limit our ability to generalize our results primarily to adolescents with cancer showing similar motivation and level of health.

A second important feasibility concern for this project is its small sample size. As previously discussed, our sample size could potentially jeopardize our statistical power, hence limiting our ability to detect the effectiveness of the intervention. However, the sample size is comparable to those of previous studies that have detected an effect of MBSR in oncology, which leads us to believe our target of 28 participants is both achievable and realistic.
We do expect recruitment challenges, specifically in terms of presenting our research to ill adolescents and their parents, convincing them to take part in this project, and the fact that pediatric cancers are less frequent than adult cancers. However, we will maximise recruitment by using multiple recruitment strategies and different avenues to publicize this study.

The risk for attrition is an additional limitation of this project. Given the target population for the study, it is possible that attrition will be observed during the process due to diverse reasons, namely deterioration of health, initiation or reinitiation of treatment rounds. Drop-outs could also occur due to the challenging nature of the intervention. Participants may conclude that the program is not what they expected or is simply too demanding for them. Further drop-outs may occur six months post-intervention, as some participants may be lost to follow-up (e.g. harder to reach, no longer motivated to participate in the project). In addition, the research team is weighing out different options to minimize attrition in the wait-list control group – namely, monetary compensation and/or additional iTunes gift cards.

**Study benefits**

In spite of possible limitations, this project will be one among very few aimed at improving quality of life, sleep and mood in adolescents living with cancer. To this day, mindfulness meditation has not been empirically tested with youth suffering from this condition. This project will help in evaluating the potential benefits of such a practice on both psychological and physical health of youth with cancer. Moreover, as psychological support programs in pediatric oncology are rare, conclusive results from this project could help in creating mindfulness-based intervention programs, in order to provide the necessary psychological help to adolescents living with cancer.
**Trial status**

This is a clinical trial with ongoing patient recruitment. Recruitment for this project has started in September 2012, and is expected to be completed by May 2013.

**List of abbreviations**

MBSR: Mindfulness-Based Stress-Reduction

MBCT: Mindfulness-Based Cognitive Therapy

**Competing interests**

Authors declare no competing interests.

**Authors’ contributions**

Authors CMH, MA and SS contributed to the design and conception of this study. Authors CMH and MV have elaborated the intervention protocol and participated in the recruitment of participants. CMH drafted the manuscript. All other authors have contributed to the revision of the initial manuscript and read and approved the final version of the submitted article.

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Figure 1. Design and Subject flow

Teenagers with cancer

Short clinical interview to screen for ongoing or lifetime severe psychopathology

Eligible → No

Yes (N=40)

Consent, Randomization and Baseline Assessment

N=20

Mindfulness-based Intervention group (8 weeks)

Post-Intervention Assessment (8 weeks)

Follow-up Assessment (6 months; N=14)

N=20

Wait-list condition (8 weeks)

Post-Intervention Assessment (8 weeks)

Follow-up Assessment (6 months; N=14)

Mindfulness-based Intervention group (8 weeks; N=14)
**Figure 2. Measures and Assessment Time-Points**

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