**Would you say that to a friend? A Randomised Pilot of a Self-Compassionate Writing Intervention in Reducing Body Image Distress in Individuals with a Visible Skin Condition**

**Study Protocol: Version 2­­­­­**

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**Introduction**

Background & Rationale

A team of researchers at Macquarie University recently developed “My Changed Body” (MyCB). This intervention is a single-session, online expressive writing exercise based on the key concepts of self-compassion: (1) self-kindness, (2) common humanity, and (3) mindfulness (Neff, 2003; Neff & Germer, 2017). MyCB has demonstrated immediate increases in self-compassion that lead to later improvements in body image disturbance in breast cancer survivors (Sherman et al., 2018). However, reports of increased body image disturbance extend beyond the oncology context, and have been found in individuals with a visible skin condition due to abnormalities in the skin (Rumsey, 2018). In this population, these body image concerns have been associated with negative psychosocial outcomes including stress, anxiety, negative emotional regulation and depression (Bowe, Doyle, Crerand, Margolis & Sahlita, 2011; Rumsey, 2018). While psychotherapeutic interventions have been developed to manage skin conditions, these are time and labour intensive with few interventions demonstrating promising results (Shenefelt, 2010; Rumsey, 2018). Therefore, there is an increasing need for an efficient and effective intervention, to address the psychological functioning in those with visible skin conditions.

More recently, Macquarie University researchers’ demonstrated that MyCB immediately increased self-compassion in individuals with visible skin conditions (Sherman, Roper & Kilby, in press). This pilot study, suggests feasibility of MyCB intervention in this population, supporting further investigation of the lasting effects of MyCB on body image distress in individuals with visible skin conditions. Future research may significantly benefit both individuals and the broader skin condition community, by providing a user-friendly intervention to address the negative psychological outcomes, such as associated with body image distress. While existing research on MyCB is based on single session intervention, no studies have yet investigated the impact of more sustained and more frequent writing sessions. Given the current MyCB findings, there is a need to determine whether the benefits currently observed can be extended by the repeated use of writing tasks. Further lacking is the comparison of a brief self-compassionate writing intervention with an objective writing control. Previously, MyCB has been compared expressive writing intervention (Sherman et al., 2018), which treatment paradigm in itself. Therefore, using an objective writing exercise would better replicate the comparison of MyCB, rather than comparing with an active psychological intervention. This control also ensures that the effect of writing as a distraction from preconceived thoughts and the time taken to complete the writing exercises are accounted for.

Objectives

We aim to assess the efficacy of multiple sessions of the “MyCB” intervention in addressing body image distress in individuals with visible skin conditions, when compared with a non-therapeutic writing task. The secondary aim of the study is to examine the impact of MyCB on negative affect, self-compassion and self-perception of the effect of the intervention.

Trial Design

A randomised pilot will be used to assess the efficacy of an online expressive writing task with specific self-compassionate writing prompts – My Changed Body (MyCB) – to improve body image concerns, self-compassion and negative affect in male and female participants with a symptomatic visible skin condition (e.g., eczema, psoriasis, acne). MyCB will be compared to an online objective writing task which will not include the specific self-compassionate writing prompts.

**Method:**

Participants

Participants will be recruited from April 2019 to July 2019 and are eligible to participate if they self-identify as the following: a) over 18 years of age, b) currently experiencing symptoms of a visible skin condition (e.g. acne, eczema, dermatitis, psoriasis, etc.) c) have experienced at least one negative event related to their skin condition, and d) had access to the internet.

Recruitment

Participants will be recruited electronically using the SONA research pool of Macquarie University first-year psychology students, in exchange for 1-hour course credit. Course credit will be will be awarded per session completed, in line with Macquarie University standards, and aim to promote retention (Ziemer, Lamphere, Raque-Bogdan, & Schmidt 2019); (1) Part 1 30 minutes = 1 credit, (2) Part 2 15 minutes = 0.5 credit, (3) Part 3 15 minutes = 0.5 credit. Participants are free to leave the study without penalty. A G\*Power ver 3.1 analysis using alpha level of 0.05, power of 0.8 and a moderate effect size indicated 95 participants are needed. The moderate effect size is based on previous literature examining the effect of self-compassionate writing on body image distress (Sherman et al., 2018; Albertson, Neff & Dill-Shackleford, 2014; Moffit, Neumann & Williamson, 2018). Given the anticipated drop out of 20% we aim to recruit 120 participants.

Procedure

*Part 1:*

Following online registration and consent, all participants complete the baseline questionnaire. Participants will then be randomly allocated to either the MyCB intervention condition or the objective writing control condition via the computer using the Qualtrics randomizer function. Participants will be blind to condition allocation. Immediately after randomization, participants will complete their assigned writing task. Those choosing not to complete the writing task can withdraw from the study by closing their internet browser, thus ending their participation.

*Part 2:*

One week following baseline questionnaire completion, researchers will email participants a follow-up questionnaire. After completing the follow-up questionnaire, participants will engage in a brief version of the previous writing exercise as per allocated condition.

*Part 3:*

Approximately one-month post baseline assessment participants will be emailed a link to the final questionnaire.

Intervention

Participants in the intervention condition accessed “MyCB” in two sessions: (1) the complete MyCB writing exercise (2) a brief version of the MyCB writing exercise. MyCB assists users in perceiving their body and visible skin condition in a caring and supportive way, by allowing them to describe their deepest thoughts and emotions. MyCB is purposefully brief to enhance the acceptability of the task, reduce time burden, and maximise the user-friendly aspects of the activity.

Firstly, participants will be granted immediate access to the complete MyCB writing exercise with specific, self-compassionate writing prompts after completing the baseline questionnaire. The complete MyCB writing exercise begins with a general description of a negative event related to changes in their body. This is proceeded by five specific self-compassionate prompts (totalling in 6 prompts) to structure their writing by beginning with a narrow focus on the negative aspects of the self, and gradually writing in a more self-compassionate perspective (i.e., considering other people’s perspectives), and finally ending with a narrow focus on the personal situation (see Table 1 for intervention prompts). Prompts will be presented in separate text boxes to assist in organising the participants writing. The complete intervention will take approximately 30 minutes to complete. Secondly, participants will access a brief MyCB self-compassionate writing task approximately one week after completing the baseline questionnaire. The brief MyCB is an extension of the complete MyCB writing task, and prompts participants to write self-compassionately (i.e. with kindness) about their personal situation.

 Participants allocated to the active control condition will complete an online objective writing task that will be administered in two sessions. This control condition mirrors the intervention condition in format and time taken to complete each writing session. Participants in the control condition will receive and initial prompt to write about a familiar room in a factual and detail-orientated way, with no reference to self-compassionate concepts. Following text boxes included the prompts to write about different aspects of the room in the same manner. The sixth and final text box asked participants to provide factual conclusion about the objects in the room (See Table 3. for control prompts). In the second administration of the brief control writing task, participants will be asked to write about another familiar room as a whole in a factual and objective way. This active control will ensure that the effect or writing itself, and the effect of time taken to complete the task of writing was accounted for.

**Table 1.** *My Changed Body* writing prompts

|  |  |
| --- | --- |
| Writing activity task | Prompt |
| 1. Introduction
 | Think about a negative event that you have experienced regarding symptoms of your skin condition that made you feel bad about yourself – something that involved sadness, embarrassment, failure, or rejection. Please set the scene and write an introduction for the negative event in the space below: |
| 1. Kindness to your body
 | Think about how your body has changed through your experience with your skin condition. Please write a paragraph about whether or not you have treated your body and yourself with kindness during this time. |
| 1. Kind advice
 | Keeping in mind how your body has changed as a result of having a skin condition, please write a paragraph showing understanding, kindness, and concern for yourself in a way you would help a friend who had undergone the experience. |
| 1. Connection with others
 | Please write a paragraph about ways in which other people also experience similar events (i.e., how other people may be feeling uncomfortable about their appearance or body). |
| 1. Awareness of the bigger picture
 | Please look at your feelings using a bigger perspective of the situation. See if you can put some space between the event and your reactions. Think about all the issues that have contributed and write about your feelings using this outlook. |
| 1. Conclusion – A letter to myself
 | Write a self-compassionate letter to yourself, perhaps extending this to a letter to all people with skin conditions. Having a skin condition, what are some of the things you’ve needed to hear about your body? What are you needing to say to yourself? What would you say to all people who are struggling with these issues? |

**Table 2.** Shortened *My Changed Body* writing prompts.

|  |  |
| --- | --- |
| Writing activity task | Prompt |
| 1. Introduction
 | Last session you were asked to write with kindness about negative event related to your skin condition, whilst considering others and the bigger picture. Lastly, you wrote a self-compassionate letter to yourself that mentioned things you needed to hear about your body and say to yourself when struggling with issues related to your skin condition.  |
| 1. A letter to myself
 | This session you will write a second self-compassionate letter to yourself. Try to write in a way that expresses kindness and understanding in relation to your skin condition. What are you needing to say to yourself? What would you say to all people who are struggling with these issues? |

**Table 3.** Control condition writing prompts.

|  |  |
| --- | --- |
| Writing activity task | Prompt |
| 1. Introduction
 | For this writing session think about this room you are familiar with in a factual and detail-orientated way. Your descriptions should be information only and not include comments regarding your thoughts or feelings about this room. Please set the scene by writing in the space below about the function of the room and where the room is located in the building (without using building name or address). |
| 1. Part 2
 | Please write a paragraph in detail about the walls, floor and size of the room. |
| 1. Part 3
 | Please write a factual paragraph describing the large objects in the room. |
| 1. Part 4
 | Please write a paragraph in as much as possible detail describing the small objects in the room. |
| 1. Part 5
 | Think about where the objects are located in the room, and remove the largest objective from the room. Describe in a factual way how the room would change. |
| 1. Part 6 – conclusion
 | Please write a factual and detail orientated conclusion about all the items in the room.  |

**Table 4.** Shortened control condition writing prompts.

|  |  |
| --- | --- |
| Writing activity task | Prompt |
| 1. Introduction
 | Last session you were asked to write about a room familiar to you. The previous writing activity asked you write and think about this room in a factual and detail-orientated way. For this writing session think about different, yet familiar, room in a factual and detail-orientated way. Your descriptions should be information only and not include comments regarding your thoughts or feelings about this room.  |
| 1. Part 2 - conclusion
 | Please write a factual and detail orientated a paragraph describing the room. This should include all the items in the room, and how they fit together to serve a purpose in the room.  |

Measurement of Treatment Effect

*Primary Outcomes*

Body Image Distress (at all-time points) – Negative aspects of body image were measured with the 7-item Body Image Disturbance Questionnaire (Cash, Phillips, Santos, & Hrabosky, 2004). This scale was chosen as it assesses body-image specific distress rather than general psychological distress. An average total score will be calculated, with scores ranging from 1 to 5 with higher scores indicative of greater body image distress.

*Secondary Outcomes*

Self-compassion (at all-time points) – Measured with the 12-item Self-compassion Scale – Short Form (Raes, Pommier, Neff, & Van Gucht, 2011). A mean score was calculated, with scores ranging from 1 to 5 with higher scores indicative of higher self-compassion.

Negative Affect (Post-treatment and all time points) – Measured with the 20-item Positive and Negative Affect Schedule (Watson, Clark & Tellegen, 1988) consisting of a 10-item momentary positive affect subscale and a 10-item momentary negative affect subscale. Scores ranged from 10 to 50 on both subscales with higher scores on each subscale representing higher endorsement of the subscales affect.

Self-perception of the effect of the intervention (measured after each writing session) – measures with five questions adapted from past expressive and self-compassionate writing literature (Ziemer et al., 2019) (a) How personal were your essays? (b) To what degree did you reveal your emotions in your essays? (c) Do you believe that writing about this topic has affected how you think about this topic? (d) Do you believe facing this topic in your writing has improved the way you feel about it? and (e) To what degree did writing about this topic make you feel understood and more accepting of your body?

*Covariates*

A range of potential covariates will be measured immediately before the writing task including demographics and medical history (age, gender, education level, skin condition type, time since skin condition onset, recipient of treatment [yes/no], perceived skin severity [from 1 “Low Severity” to 5 “High Severity”]) and previous experience with therapeutic writing task [yes/no].

Data Analysis

*Study Objectives and Statistical Analyses*

The primary objective is to assess whether multiple sessions of MyCB self-compassionate writing will decrease body image distress in individuals with visible skin conditions. This work builds from prior work with MyCB that suggests MyCB produces immediate increases in self-compassion that lead to later improvements in body image disturbance in a sample of breast cancer survivors (Sherman et al., 2018). Additionally, a pilot study conducted by Sherman, Kilby & Roper (in press) suggests that MyCB results in immediate shifts in self-compassion in individuals with visible skin conditions. The secondary aim was to assess the effect of *MyCB* on self-compassion, negative affect and self-perception of the effect of the intervention.

 All analyses will be performed in SPSS version 25.0 (IBM Corp., 2017) unless otherwise specified. Significance will be set at 0.05 for all tests. Descriptive analyses will outline sample characteristics. Chi-square and *t*-test analyses will be used to compare baseline demographics, medical history and previous experience with therapeutic writing task across conditions, and identify covariates for inclusion in subsequent mixed-model analyses. Main analyses will be based on a group (two conditions) by time (three assessments: baseline, 1 week and 1 month) randomised design within an intent-to-treat framework. Linear mixed models analyses will be used to assess effects of the intervention (condition) over time, controlling for baseline outcome levels and identified confounding variables. Fixed effects will include Time, Condition and the interaction of Time\*Condition, baseline outcome levels and identified confounding variables. Random effects for a participant-specific random intercept will account for within-participant correlation. We will use a two-sided significance level of α=.05 for all analyses.

Harms:

Psychological discomfort: MyCB requires participants to write about a negative event related to their skin condition. Based on past research of MyCB intervention (Sherman et al., 2018) the likelihood of causing psychological discomfort in response to the negative event is minimal. To mitigate this risk, the researchers will outline the requirement to write about a negative event in the invitation to participate in the study to manage participant expectation. Additionally, if participants are not comfortable completing the writing intervention, they have the option to simply close their web-browser and discontinue with the study.

**Ethics & Dissemination:**

*Research ethics approval:* This protocol is subject to approval from the Human Research Ethics Committee.

*Protocol amendments:* The information provided reflects the current protocol and any planned modifications will be communicated to the REC and all relevant parties.

*Consent:* Consent will be obtained (Please see Appendix 1. Participant Consent Form).

*Confidentiality:* Data will be collected in Qualtrics. All data will be kept in its raw form in Qualtrics. Data will be downloaded, de-identified and stored on KS’s password protected OneDrive account for a period of at least 5 years since the last publication. Only those mentioned on the current protocol version will have access to the data. This method of collection, sharing and storage aims to protect confidentiality of participants.

*Dissemination policy:* The results of the study will be disseminated in publication.

**References**

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**Appendix 1:** Participant Information and Consent Form



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**Participant Information and Consent Form**

**Would you say that to a friend?**- A study of feelings towards your body when experiencing symptoms of a visible skin condition.

**What is the purpose of this study?**

You are invited to participate in an online study of feeling towards your body when experiencing symptoms of a visible skin condition. The purpose of the study is to assess the effectiveness of a brief writing exercises in addressing the way you think and feel about your skin conditions and overall appearance. This project aims to extend previous research which demonstrated that a brief writing intervention has effectively addressed body image concerns in the oncology context.

The study is being conducted by Brittany Smith (Brittany.smith4@students.mq.edu.au) to meet the requirements of the Bachelor Honours studiesunder the supervision of Prof Kerry Sherman (Kerry.Sherman@mq.edu.au*)* Deputy Head Dept. Department of Psychology.

**What will I be expected to do?**

If you decide to participate, you will be asked to complete a two-part intervention. To be eligible for study participation you need to: a) be 18 years of age or over, b) be currently experiencing a visible skin condition (e.g., eczema, acne, dermatitis), c) have experienced at least one negative event related to your skin condition (e.g., feeling humiliated, embarrassed, sad), and d) have access to the internet.

This study has two parts.

Part 1:

The first part is an online questionnaire to be completed after providing informed consent, and then follow up questionnaires 1-week and 1-month after signing up to the study. You will be asked about some background information and your contact details (name, student number and email address) in the first questionnaire.  You will also be asked about your current feelings and the impact of the visible symptoms of your skin condition upon your body. Your contact details will be used to email web links so that you can complete questionnaires on the two follow up occasions.  It is expected that you will need no more than 15 minutes to complete each on-line questionnaire.

Part 2:

This is an online writing activity which will be accessed in two sessions: (1) immediately after sign-up; and (2) 1-week following. In the first session you will be allocated one of two online writing activities that include 6 prompts to guide your writing. You will then be given approximately 20 minutes to complete your assigned writing task. The second session is a brief version of the previously assigned writing activity. We expect this to take 10 minutes to complete.

PLEASE NOTE: The researchers will not be able to read your writing activity. Researchers will only have access to the questionnaires, which will not be identifiable.

Reminder emails will be sent to you in about 1 week and 1 months’ time to complete the above.

Remuneration:

Course credit will be will be awarded as per Macquarie University standards, for completion as follows: (1) Part 1 30 minutes = 1 credit, (2) Part 2 15 minutes = 0.5 credits, (3) Part 3 15 minutes = 0.5 credits.

**Will my participation be confidential?**

Any information or personal details gathered in the course of the study are confidential, except as required by law. No individual will be identified in any publication of the results. Only project researchers will have access to the data. A summary of the results of the data can be made available to you on request (via email Brittany.smith4@students.mq.edu.au). There is no intention that the data will be made available for use in future Human Research Ethics Committee-approved projects.

Participation in this study is entirely voluntary: you are not obliged to participate and if you decide to participate, you are free to withdraw at any time without having to give a reason and without consequence.

**What you are agreeing to:**

By agreeing to participate in this study you are acknowledging that you have read and understood the information above and any questions you have asked have been answered to your satisfaction. You acknowledge that you are agreeing to participate in this research, knowing that you can withdraw from further participation in the research at any time without consequence. You acknowledge that you will be emailed a copy of this form to keep.

The ethical aspects of this study have been approved by the Macquarie University Human Research Ethics Committee. If you have any complaints or reservations about any ethical aspect of your participation in this research, you may contact the Committee through the Director, Research Ethics & Integrity (telephone (02) 9850 7854; email ethics@mq.edu.au). Any complaint you make will be treated in confidence and investigated, and you will be informed of the outcome.

*This is an online study. You are under no obligation to participate and will not be given the study URL until you have signed up for the study. In order to sign up for the study, you must agree to the terms of participation noted in the information and consent form. This includes not receiving credit for participation until the end of the survey. You are free to stop the survey at any stage; but, you will not receive credit for participating unless you complete the entire survey. As a participant, you are obligated to answer all questions accurately and honestly. Answering fictitiously or haphazardly jeopardises the quality of the research.*

*If you terminate your research participation due to adverse circumstances, please contact the researcher.*

*As a research participant you are responsible for:*

–        *Completely reading information and consent forms*

–        *Carefully weighing the risks and benefits of participation*

–        *Knowing when, where, and for how long participation is required*

–        *Talking to the researcher when concerns arise*

–        *Fulfilling the responsibilities as described in the information and consent forms*

**What can I do if I would like to speak more about my feelings?**

If you would like to receive emotional support or further discuss your experiences, Lifeline Counselling Service (phone number 13 11 14) can provide more help. This service is provided free of charge.

To express your consent to participate, please fill in the below application.

**Please note that all identifying information will be kept separate from your responses in this study, and will only be used to send you the 1 week and 1 month follow-up questionnaire.**

|  |  |
| --- | --- |
| First name |  |
| Last name |  |
| Email |  |
| Email confirmation  |  |

**Do you want to participate in this study?**

|  |  |
| --- | --- |
| Yes, I am happy to participate in this research |  |
| No, I have changed my mind and no longer wish to participate |  |

**(INVESTIGATOR'S [OR PARTICIPANT'S] COPY)**