Managing Chronic Pain Through the Web: Evaluating the Efficacy of a Web-based Acceptance and Commitment Therapy (ACT) Intervention

2018-10-15

One in five Canadians currently lives with chronic pain (CP; Reitsma et al., 2011) and the prevalence is expected to increase 70% by 2025 due to the aging population (Schopflocher, 2003). The daily experience of pain is often accompanied by important psychosocial changes. For example, CP has been associated with the onset of anxiety and depressive disorders (Gerrits et al., 2014) as well as feelings of anger and injustice (Scott et al., 2013). Research has also shown that a person with CP is twice more likely to commit suicide than a person without CP (Tang & Crane, 2006), which demonstrates the extent of suffering that people with this condition can experience.

At present, access to treatment for CP in Canada is limited (Lynch et al., 2011) and is considered a major challenge. For example, the average wait-list time for access to care is over a year in more than one third of publicly funded centres for pain and some could even go up to five years (Lynch et al., 2011; Peng et al., 2007). Furthermore, many areas of the country do not have interdisciplinary pain management centres (Lynch et al., 2011). Yet, access to pain management is a fundamental human right as stated in the Declaration of Montreal (Brennan et al., 2007; IASP, 2017). In addition to challenges associated to access to treatment for pain, medical/physical treatments are often not entirely effective in reducing one's pain when it is chronic. For example, only 30% of people who take pain-relief medication would see an improvement in their condition, while 70% of people continue to experience pain on a daily basis (Stahl, 2013).

Acceptance and Commitment Therapy ("ACT"; Hayes et al., 2012) is an empirically supported treatment with "strong research support" for CP by the *American Psychological Association* (APA, 2013). The experience of injustice has recently been conceptualized within the ACT psychological flexibility model (Scott et al., 2013b). ACT has been shown to help improve functioning and quality of life despite pain, and could potentially help mitigate the impact of perceived injustice on adverse pain outcomes (e.g. disability, depressive symptoms). Given the evidence of the effectiveness of ACT with CP, there are increasing efforts to improve the accessibility of this type of treatment. In particular, internet-delivered versions of ACT for CP are promising because they offer a cost-effective treatment option that usually requires little support from a therapist, and can be widely accessed.

Despite promising results (Bring, Åsenlöf, & Söderlund, 2016; Trompetter et al., 2016), further studies are needed to evaluate the effects of self-help interventions like ACT, including on physical and emotional functioning (Brown et al., 2016, Eccleston et al., 2014). Given the recent nature of self-help interventions in a population with chronic pain, other studies need to support their effectiveness. In addition, there are no studies that compared a self-help Web-based ACT intervention to a bibliotherapy intervention (French, Golijani-Moghaddam, & Schröder, 2017).

Objectives:

Evaluate the effectiveness and change processes of a web-based intervention program with minimal therapeutic contact, compared to a bibliotherapy and an education program based on brochures in adults with suffering of chronic pain.

Hypothesis 1: It is expected that the web-based self-help intervention generates a significant reduction in pain-related disability greater than the control group (education).

Hypothesis 2: It is expected that the bibliotherapy self-help intervention by bibliotherapy will result in a significant reduction in pain-related disability (primary variable) greater than the control group (education).

Hypothesis 3: It is expected that a web-based intervention will be associated with a greater reduction in pain-related disability (the primary variable) than bibliotherapy.

Hypothesis 4: It is expected that self-help Web-based interventions will lead to a significant improvement in the quality of life above the control (education) group.

Hypothesis 5: It is expected that bibliotherapy will significantly improved the quality of life superior to the control group (education).

Hypothesis 6: Self-help interventions are expected to result in a significant reduction in anxiety and depressive symptoms compared to the control (education) group.

Hypothesis 7: Self-help interventions with bibliotherapy are expected to result in a significant reduction in anxiety-depressive symptoms compared to the control (education) group.

Hypothesis 8: Results on primary (incapacity) and secondary variables (quality of life, anxiety-depression) will remain at 3 and 6 months and will be superior to education brochure (control group).

Hypothesis 9: The flexibility process is expected to be a mediator of change in the primary (disability) and secondary variables (quality of life, anode-depressive symptoms).

Participants and procedure: Recruitment will be done in collaboration with the Quebec Association of Chronic Pain (AQDC), the Quebec Pain Research Network (RQRD), the Quebec Society of Fibromyalgia (SQF), Migraine Quebec, the Pain Clinics of Quebec. Quebec (28 including the CHUM, distribution of maps and billboards) and social networks Facebook (Facebook page with paid advertising). Participants will be notified of the study via email. If they have an interest in the study, they will click on a link that will take them to the information and consent form and will be asked questions about the inclusion criteria.

- Be over 18 years old Living in Quebec
- Have a daily pain (greater than 4 out of 10) for more than three months that is not associated with cancer;
- Have a reading and writing ability of French equivalent to a secondary 2;
- Have Internet access at home and an email address;
- Never have ACT-type psychotherapy or regular meditation in mindfulness, and have not read Frédérick Dionne's book "Liberez-vous de pain par meditation et ACT";
- Have a stable medication for at least one month, if necessary.
- Being emotionally stable

If they do not meet the criteria, they will be refer to a resource page and will be asked to leave their name as needed to be referred to relevant resources. If people meet the inclusion criteria, they will be asked to complete the pre-test questionnaires, which will confirm their participation in the study.

Desis: A randomized control group trial with a sample of 300 presenting chronic pain, ie 100 persons for each experimental groups (web-based and bibliotherapy) and 100 persons for control group (education brochure).

Arms:

- Web-based, N = 100
- Bibliotherapy, N = 100
- Education brochure, N = 100

The estimate includes four measurement times (before and after the intervention, and two times at follow up (after 3 and 6 months) to assess the impact of the intervention in the longer term. The proposal will include three conditions, a group receiving a self-help web-based intervention, a group receiving a book-based intervention and a group receiving pain education brochures. Participants in all three groups receive 15-minute telephone calls from psychology students before and at week 3, a weekly email explaining the tasks to be completed, a discussion forum, access to an assistant to answer questions of a technical nature. These components aim to support participants' therapeutic approach and adherence to treatment (van Ballegooijen et al., 2014). Here is the content of the meetings for the 8 modules or weeks

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Content of each module.

Week 1	Information about pain and ACT
Week 2	Values
Week 3	Learning to meditate

Week 4	Committed action
Week 5	Willingness to have pain
Week 6	Defuse from thoughts
Week 7	Pacing
Week 8	Conclusion

Instruments: All questionnaires will be self-administered online following an email sent. A hyperlink will automatically direct them to the UQTR Interactive Question Banking (IBQ) website. The completion time is evaluated between 25 and 30 minutes for each measurement period.

Participants answered questions related to socio-demographic information such as their age, education, daily occupation, and annual income. Participants also answered a series of questions related to pain, such as the diagnosis of chronic pain and the use of pain relief medication. Notably, participants were asked to rate the average pain they experienced in the past week on a numerical rating scale ranging from 0 (*no pain)* to 10 (*unbearable pain*). According to previous research, this scale is a reliable measure of pain intensity

Primary variable:

BPI; Brief Pain Inventory (Interference Scale). This 10-item questionnaire evaluates the severity and interference of pain in daily activities. On a Likert scale ranging from 0 = does not interfere to 10 = interferes completely, participants are asked to rate the degree to which pain interfered with various activities in the past week (e.g., social activities, work, mood, etc.). A higher average score represents higher levels of pain interference on daily function. Internal coherence of this scale is good (α = 0,88).

Secondary variables:

Quality of life:

The World Health Organization Quality of Life-Brief (WHOQOL-BRIEF; WHOQOL; Group, 1998) is a self-reported measure of 26 items assessing quality of life in terms of physical and psychological health, social relationships and social functioning. environment. This instrument has demonstrated good levels of internal consistency for its subscales (α = .66 to α = .80) and adequate test-retest reliability (r = .75). The French version of the instrument offers high consistency (Baumann, Erpelding, Régat, Collin, & Briançon, 2010).

Anxiety and depression:

The Hospital Anxiety Depression Scale (HADS; Zigmond & Snaith, 1983; French version: Bocéréan & Dupret, 2014). This 14-item questionnaire evaluates psychological distress according to two 7-item subscale-measuring anxiety and depressive symptoms in non-psychiatric hospital contexts. Items are scored on a 4-point Likert scale ranging from 0 to 3. An example of items is “I feel tense or wound up.

Process measures:

Multidimensional Psychological Flexibility Inventory (24 items; MPFI). Psychological flexibility and inflexibility were measured with the French version of the MPFI-24 already described. This self-report questionnaire was developed by Rolffs, Rogge and Wilson (2016) and offers a response on a six-point Likert scale (Never / Always true). This tool has 12 distinct dimensions of flexibility or psychological influence (6 minutes).

Chronic Pain Self-Efficacy Scale (FC-CPSES, 6 items). Self-efficacy is an important aspect to consider when evaluating the benefits of an intervention to improve self-management of chronic pain. This instrument has an internal consistency evaluated at more than α = 0.86. Better self-efficacy scores are associated with a better quality of psychological life, less severe pain symptoms and less dramatic tendencies (P <0.05), which supports the convergent validity of this tool (2 min).

Chronic Pain Acceptance Questionnaire (CPAQ-8; McCracken, Vowles, & Eccleston, 2004; French version: Scott, Bernier, Garland, & Sullivan, 2003). The CPAQ-8 assesses a person’s acceptance of the experience of pain using two four-item subscales: activity engagement, which evaluates the degree to which behaviours are limited or restricted by pain, and pain willingness, which evaluates the degree or effort directed at controlling pain. Items are scored on a 7-point Likert scale ranging from 0 = never true to 6 = always true. An example of items is “I am getting on with the business of living no matter what my level of pain is.” Scores for the pain willingness subscale must be reversed before calculating a total score.

Questionnaire filled each week:

Weekly journal (7 items):

Participants will be invited to answer this short questionnaire before accessing the contents of the module for the week. It is an abbreviated tool with 3 items on a Likert type scale (0 = never, 6 = always) that assess flexibility processes (open, aware and active). In addition, to assess dependent variables throughout the process, 4 questions measuring disability, pain intensity, depression, and anxiety were added to the questionnaire. Thus, this questionnaire includes a total of 7 items designed to measure the evolution of the variables of interest over time, and the completion time is evaluated at 2 minutes.

Follow up only:

The Satisfaction Questionnaire (QS-8, Sabourin, Pérusse, & Gendreau, 1989) is the French version of Client Satisfaction Questionnaire-8 (CSQ-8, Larsen, Atkinson, Hargreaves, & Nguyen, 1979). This instrument is a self-reported eight-item measure to assess satisfaction with health care services. The response format is Likert type (1 to 4). A high total score indicates greater satisfaction. He demonstrated good internal consistency (α = .89) (Sabourin, et al., 1989).

System Usability Scale (SUS; Brooke, 1996) is a usability questionnaire that has been adapted into French. It will be sent to participants in the Web-based intervention only after the eight weeks of the program in order to measure their level of satisfaction with the program. This questionnaire contains 10 items (eg: I find that the features of this online workshop are well integrated) and responds on a five-point Likert scale (not at all strongly agree). A question will be added to ask participants about the number of modules they have completed. This questionnaire will take less than two minutes to complete.

Follow up only (week 20 and 28):

Patient Global Impression of Change (PGIC, 5 items).
This tool assesses the level of change in pain, functioning, quality of life and psychological well-being factors over the past three months. They are evaluated on a 7-point Likert scale from 0 (significantly increased) to 6 (significantly decreased). A fifth item evaluates pain relief in the past three months and is measured on an ordinal scale ranging from 0 (no relief) to 100 (complete relief). This tool is increasingly used to assess the impact of change in the lives of patients with chronic pain (1 minute).

Data analysis:

The sample size for this study is optimized to compare the expected results on post-treatment pain interference. In addition, we expect the effect size for the web-based group to be higher than for the bibliotherapy. Randomized trials using an ACT intervention for chronic, web-based pain reported effect sizes of d = 0.33 (Trompetter et al., 2014), d = 0.56 (Buhrman et al., 2013).) and d = 0.58 (Lin et al., 2017) with respect to pain-related interference. Considering the attrition of about 25% (between pretest and stimulus), based on the calculations of Lin et al. (2014), to obtain a statistical power of 80% (5%) and to detect an average effect size (d = 0.40), which proves clinically satisfactory for this type of study, a sample of 100 participants per group (300 in total) is required according to our calculations on G * power.

Generalized linear models with a group-by-time interaction will be used to compare the time conditions of the ACT-guided group with bibliotherapy and education brochures. Dichotomous arrival points will be modelled using a binomial distribution and a log link while a normal distribution and identity link will be used in the case of continuous arrival points. The generalized estimating equations approach will take into account the correlation between measurement times. Contrasts, defined a priori based on research hypotheses, will be used to make comparisons between groups and different measurement times. The analyzes will be performed according to the intent to treat.

Considering the current waiting lists for accessing psychological services in the public system, the social relevance of developing the accessibility of a self-help intervention by the Web is undeniable. We hope that our statistical data will support the development of new practices in the management of patients with chronic pain. The innovation will provide access to effective therapy in a short time and at low cost with a cost-benefit ratio.

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