

Clinical Pain Research

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A feasibility trial of online Acceptance and Commitment Therapy for women with provoked vestibulodynia

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Abstract

Objectives: Acceptance and Commitment Therapy (ACT) is an established treatment for chronic pain. However, it is a form of treatment that have not yet been applied much in the treatment of persistent vulvar pain disorders. This study examines the feasibility and preliminary effects of online ACT for patients with provoked vestibulodynia.

Methods: Women diagnosed with provoked vestibulodynia were assigned randomly either to online ACT or to a waitlist control group. Feasibility was assessed in terms of recruitment potential, treatment credibility, completions rates, retention in trial, and data quality. Participants completed measures of pain with sexual activity, sexual functioning, emotional and relational adjustment, and potential treatment processes before and after treatment.

Results: Of the 111 women who were invited to participate in the study, 44 were included (39.6 % recruitment rate).

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Thirty seven participants (84.1 %) completed the pre-treatment assessment. Participants who received online ACT rated treatment credibility positively, and completed on average 4.31 (SD=1.60) of the six treatment modules. Of participants, 34 provided post treatment data, giving a trial retention rate of 77 %. Effects of online ACT, as compared to waitlist, were large for pain acceptance and quality of life, medium for anxiety and pain catastrophizing, and small for sexual satisfaction, pain with sexual activity, and relationship adjustment.

Conclusions: With some adjustments to recruitment procedures, a full scale randomized controlled trial of online ACT for provoked vestibulodynia appears feasible.

Keywords: Acceptance and Commitment Therapy; Cognitive Behavioral Therapy; internet-based intervention; sexual dysfunction; vestibulodynia; vulvodynia

Introduction

There is growing evidence that Acceptance and Commitment Therapy (ACT) [1], a third generation Cognitive Behaviour Therapy (CBT), is associated with improvements in disability and emotional functioning in people with chronic pain [2]. Despite emerging support for the effectiveness of CBT for persistent idiopathic vulvar pain, also called vulvodynia [3–6], the applicability of ACT as a treatment for women with vulvodynia has not yet been examined in a published study.

The most common subtype of vulvodynia, provoked vestibulodynia (PVD), is estimated to affect approximately 8 % of adult women [7–9]. The primary symptom of PVD is pain at the vaginal vestibule, occurring in response to contact that typically would not cause pain sensations [10]. Women with PVD commonly experience pain with sexual activity, particularly intercourse, but also in a range of daily activities, such as riding a bicycle or wearing tight fitting clothes [11]. They naturally report more emotional distress and concerns relating to sexual functioning, and less satisfaction, than

women without vulvar pain [12–14]. ACT aims to reduce the negative impact of pain on important areas of functioning and wellbeing. The treatment goal is to increase psychological flexibility, which can be described as a combination of acceptance, mindfulness, and values-based action [15]. Evidence from prospective survey studies shows that facets of psychological flexibility are significantly correlated sexual functioning, pain-related interference and depression in women with persistent vulvovaginal pain [16, 17].

Although forms of CBT are recommended for the treatment of vulvodynia [18], previous findings suggest that only a portion of those with persistent vulvar pain access any treatment at all. Approximately 40 % of women with vulvodynia refrain altogether from seeking help, in many cases because of stigma associated with the conditions [7, 19, 20]. Of those who do seek care, very few receive psychological treatment [21]. This indicates that further efforts are needed to improve treatment access for women with vulvodynia, and one way to do this is to provide treatment online [22]. Online treatments have the advantage of providing a sense of privacy that can help overcome stigma barriers to treatment [23]. A meta-analysis of comparative studies indicate that online CBT is equally effective as CBT delivered in person for a number of psychiatric and somatic conditions [24]. Studies evaluating online ACT for chronic pain specifically, have shown that these treatments are feasible and acceptable [25, 26]. They are associated with improvements in pain, pain interference, and emotional functioning in a range of pain conditions, including mixed samples of varying chronic pain [27–30] and fibromyalgia [31]. Still, none of these studies provided evidence for ACT in PVD.

To meet demands for treatments for PVD that can be readily implemented in clinical practice, carefully designed and adequately powered trials are needed. To prepare for these, earlier stage trials are needed. This study aims to examine feasibility questions for a larger randomized controlled trial evaluating the effects of online ACT for vulvodynia. Specifically, the study examines recruitment potential, treatment credibility, completions rates, retention in trial, and data quality. A secondary aim was to perform preliminary analysis of the effects of ACT on vulvodynia outcome and process measures.

Methods

Design

The study was a randomized controlled feasibility trial. Participants were assigned randomly (www.random.org) either to online ACT or to the waitlist control group. Participants allocated to the control group

received the treatment after the study was completed. They completed online assessments at pre-treatment and at posttreatment, using the trial platform. The aim was to achieve a sample size of 26 participants in each group. This sample size is in line with recommendation for feasibility studies assuming in the main trial a small effect size and a power of 80 %, allowing an attrition rate of 20 % [32]. The study was approved by the Regional Ethical Review Board in Uppsala, Sweden (ID Number 2015/31).

Participants

Participants were recruited at the Women's Health Clinic at Uppsala University Hospital in Sweden. Women previously diagnosed and treated for PVD at the clinic were identified through a search of medical records and invited to participate in the study. Inclusion criteria were [1] PVD of at least 6 months duration, where the diagnosis was confirmed by structured telephone screening interview [2], >18 years of age, and [3] access to the internet. Exclusion criteria were [1] other ongoing treatment for vulvodynia [2], insufficient language skills to complete the treatment in Swedish [3], severe, acute, or untreated psychiatric disorders, suicidality, or other conditions requiring treatment. One hundred and 11 potential participants were identified and invited to the study and 47 (42.3 %) agreed to participate and were assessed for inclusion by telephone interview. Forty-four (39.6 %) met criteria for inclusion to the study and agreed to participate, and they constitute the sample in this study. Figure 1 shows a flow diagram depicting recruitment and allocation of participants.

The participants were between 22 and 45 years old, with a mean age of 26.86 years ($SD=5.27$). The majority of participants had partners (91.9 %) at the time of the study. The mean age of pain onset was 22.00 ($SD=5.43$) and most participants had secondary PVD ($n=27$, 73.0 %). Approximately 50 % of the participants had at least one pain complaint in addition to PVD ($n=19$, 51.4 %). Thirty (81 %) participants met the cut-off for sexual dysfunction established for the Female Sexual Function Index [33]. Table 1 shows background characteristics of the participants.

Procedure

Potential participants were invited to participate in the study by mail. The letter contained information about the study and consent forms. All potential participants were also contacted by telephone. Those who confirmed an interest to participate in the study completed the eligibility screening interview. Eligible participants were then allocated to a trial arm. Participants receiving online ACT were informed about the internet platform, where they could access the treatment programme and complete the study measures. Both groups completed assessments before the start of treatment and at the end of treatment, 6–7 weeks later. The online ACT-group also completed a measure of treatment credibility after the first treatment module. Participants in the treatment group were randomized to one of four therapists. The therapists were students in their last term of a 5-year clinical psychology programme, trained in CBT. They received weekly supervision by a researcher and clinical psychologist in the research group (M.B).

Treatment

Participants in the treatment group received online ACT with therapist support. The treatment program was based on the protocol detailed by

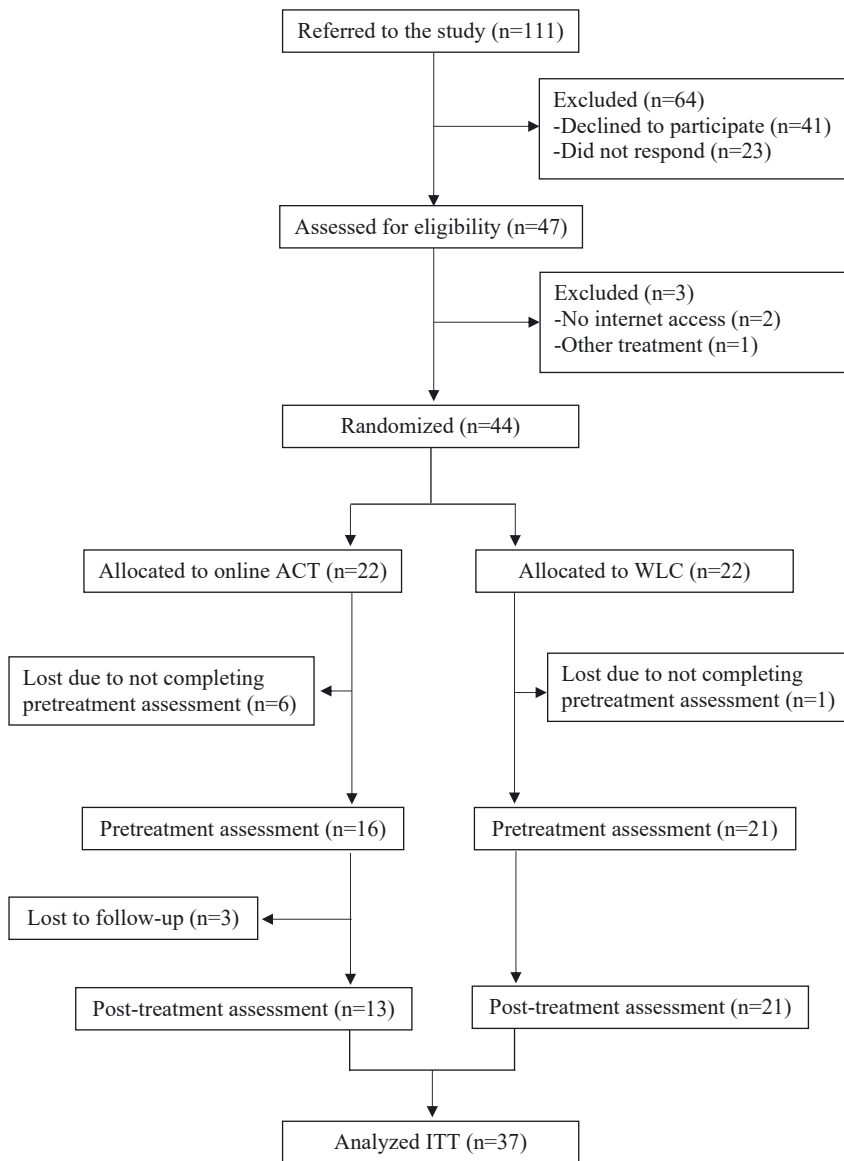


Figure 1: Flow chart of inclusion and retention

Buhrman et al. [27] and adapted for PVD in collaboration with staff at the Women's Health Clinic. It consisted of six modules containing text and assignments, informational videos, and audio files including guided experiential and mindfulness exercises. The first module contained information about PVD, pelvic floor function, and ACT. The remaining modules pertained to the following themes: control and willingness, values, thoughts and feelings, willingness and acceptance, and maintenance of achieved treatment gains. All modules contained mindfulness exercises. Participants were encouraged to work with one module per week and complete the associated assignments. The aim of therapist support was to encourage engagement in the treatment. Therapists provided written feedback on queries and assignments, provided motivation for exercise and assignment completion, and developed a supportive alliance with participants, such as through the use of validation.

Study measures

Feasibility measures: Feasibility was assessed using data on recruitment rate, treatment completion, retention in trial, missing data, and treatment credibility. Data were compared against feasibility criteria set by the authors or by comparisons with data from prior trials of online ACT. For recruitment, the criterion for feasibility was to recruit 26 participants within a period of four weeks. The threshold for treatment completion was 75% of participants completing 3 of the 6 treatment modules or more. Retention to trial was assessed in relation to attrition rates in prior trials on online ACT, with a goal of achieving comparable or lower rate of attrition. Assessment of treatment acceptability was based on the Treatment Credibility Scale (TCS) [34]. The TCS contains five items rated on a ten-point scale, with higher scores indicating greater

Table 1: Participant characteristics at baseline.

		ACT	WLC
		<i>M</i> (SD) or n (%)	<i>M</i> (SD) or n (%)
Age		25.13 (2.99)	28.24 (6.07)
Country of birth	Sweden	16 (100.0)	20
	Other	0 (0.0)	1 (0.1)
Relationship status	Single	0 (0.0)	3 (14.3)
	In a relationship	8 (50.0)	7 (33.3)
	Living with partner or married	8 (50.0)	11 (52.4)
Children		1 (6.3)	5 (23.8)
Years of education	12 years	3 (18.8)	5 (23.8)
	12–15 years	5 (31.3)	4 (19.0)
	15–18 years	4 (25.0)	7 (33.3)
	>18 years	4 (25.0)	5 (23.8)
Employment status	Employed full time	5 (31.3)	8 (38.1)
	Employed part time	6 (37.5)	6 (28.6)
	Student	4 (25.0)	7 (33.3)
	Unemployed	1 (6.3)	0 (0.0)
Age of PVD onset		18.50 (3.23)	21.53 (5.54)
PVD subtype	Primary (lifelong)	4 (25.0)	6 (28.6)
	Secondary (acquired)	12 (75.0)	15 (71.4)
Medication	Topical treatment (lidocaine)	5 (31.3)	4 (19.0)
	Antidepressants	1 (6.3)	1 (0.1)
Other pain complaints	Head, neck or shoulder pain	7 (43.8)	10 (47.6)
	Lower back or pelvic pain	6 (37.5)	7 (33.3)

treatment credibility and expectancy for improvement. We considered credibility ratings in the top half of the numerical scale as reflecting adequate acceptability.

Pain and sexual functioning: Sexual functioning and pain outcomes were assessed using the Female Sexual Function Index (FSFI) [35] and The Female Sexual Distress Scale-Revised (FSDS-R) [36]. The FSFI assessed level of sexual function including six subscales: Desire, Sexual arousal, Lubrication, Orgasm, Satisfaction and Pain. Each item is rated on a scale of 0 or 1 to 5, with higher scores reflecting better sexual function *and less pain*. A full scale score [2–36] is obtained by adding weighted subscale scores together. The FSDS-R assessed distress related to sexual concerns, such as feeling unhappy or worried about sex. The FSDS-R has a total score range of 0–52 with higher scores reflect greater distress.

Process measures: Measures of acceptance and pain catastrophizing were included to assess effects of treatment on potential treatment processes. The Chronic Pain Acceptance Questionnaire (CPAQ) [37] assessed pain acceptance, on two subscales reflecting engagement in valued activities and willingness to experience pain. The range of the total score is 0–120, with higher scores representing greater acceptance. Pain catastrophizing was assessed with the Pain Catastrophizing Scale (PCS) [38]. The PCS contains 13 items reflecting excessively negative and

ruminative thinking about pain. The full scale score ranges from 0 to 52, and higher score indicate a higher level of catastrophizing.

Emotional and relationship adjustment: Emotional and relationship adjustment were evaluated with measures of psychological distress, life satisfaction, and relationship satisfaction. Psychological distress was assessed using the two subscales of the Hospital Anxiety and Depression Scale (HADS) [39]. The subscales measure the presence of anxiety and depression, each on a scale of 0–21. Higher scores reflect more severe anxiety and depression. The Satisfaction with Life Scale (SWLS) [40] was used to measure life satisfaction. The SWLS contains five items rated on a seven-point scale, giving a maximum total score of 35. Higher scores indicate greater life satisfaction. Relationship satisfaction was assessed using the revised Dyadic Adjustment Scale (rDAS) [41]. The rDAS contains 14 items and scores range between 0 and 69, with higher scores indicating greater relationship satisfaction.

Data analyses

Descriptive statistics were used to characterize the sample at baseline. The treatment and control groups were compared on background characteristics and outcome measures at baseline, using independent samples T-tests and χ^2 -tests. Feasibility was determined by presenting descriptive statistics and comparing data against feasibility criteria detailed above. Treatment effects were determined using mixed between-groups and repeated measures ANOVA, and effect size calculations. Effect sizes of 0.2, 0.5, and 0.8 were classified as small, medium, and large, respectively [42]. An intention-to-treat approach with multiple imputation was used to address missing post-treatment values ($n=3$). Analysis were repeated using only data from participants who completed the posttreatment assessment, yielding similar results, so only ITT-analysis are presented here.

Results

Feasibility outcomes

Of the 111 women who were invited to participate in the study, 41 (36.9 %) declined to participate and 23 (20.7 %) did not respond to the invitation. Three (2.7 %) met exclusion criteria (lack of internet access or other ongoing treatment). Ultimately, 44 were included, 39.6 % of those invited. Sixteen participants (72.7 %) in the treatment group and 21 participants (95.5 %) in the control group completed the pre-treatment assessment. Treatment credibility ratings after the first module gave a mean score of 33.87 (SD=8.83) on the TCS. Mean ratings on separate items ranged between 7.73 (SD=2.78) and 6.33 (SD=2.22). Thirteen participants (81.3 %) in the treatment group completed three of the six treatment modules. On average, they completed 4.31 (SD=1.60) modules. Three participants (18.8 %) did not complete posttreatment assessments. Thirty-four participants in total provided post treatment data, 77 % of those allocated.

Treatment effect on clinical outcomes

Between-groups comparisons on outcome and process measures showed no significant differences between the groups at baseline, with the exception of a lower level of sexual desire in the control group ($t=2.44$ [35], $p=0.020$). Results from analyses examining the effect of treatment on clinical outcomes show no effects of online ACT on levels of sexual desire, arousal, lubrication and orgasm, and small effect on sexual satisfaction and pain. Large and moderate effects on treatment processes were observed for pain acceptance and pain catastrophizing, respectively. Results from analysis of treatment effects on emotional and relationship adjustment revealed a large effect of online ACT on quality of life, a moderate effect on anxiety, and a small effect on depression and relationship adjustment. Significant interaction effects between time and group were observed for quality of life, pain acceptance and pain catastrophizing. See Table 2.

Discussion

This study examined the feasibility of a larger RCT of online ACT for women with vulvodynia, and provide preliminary effect size estimates for improvements in sexual functioning, potential treatment processes, and personal adjustment. In this trial, the target sample size was not met within the set time frame for recruitment. While we now have experience and an estimate for recruitment capacity, in retrospect our target was probably over ambitious. Better recruitment capacity or rate may require additional recruitment methods in future, such as recruiting at multiple sites or by adverts [43]. Still, the recruitment rate of eligible potential participants was 39.6%, which is a higher rate than two previous trials of online ACT [27, 28]. Participants receiving treatment rated treatment credibility items on the positive end of the scale, suggesting that most individuals perceived this ACT intervention as acceptable and potentially helpful. Participants completed on average four of the six treatment modules, and

Table 2: Mixed ANOVA examining treatment effect on clinical outcomes.

		ACT (n=16) M (SD)	Control (n=21) M (SD)	MS	F	p-Value	d
FSFI desire	Pre	5.94 (2.05)	4.38 (1.83)	0.22	0.17	0.680	0.14
	Post	5.73 (2.23)	3.96 (1.69)				
FSFI arousal	Pre	13.38 (5.52)	11.86 (5.16)	1.93	0.15	0.698	0.13
	Post	13.56 (4.74)	11.38 (5.71)				
FSFI lubrication	Pre	14.44 (4.90)	12.10 (6.47)	0.02	<0.01	0.975	0.01
	Post	14.95 (4.78)	12.55 (6.30)				
FSFI orgasm	Pre	10.75 (4.20)	8.62 (5.13)	3.95	0.57	0.454	0.23
	Post	10.74 (3.87)	7.68 (4.64)				
FSFI satisfaction	Pre	9.31 (3.50)	8.43 (3.72)	4.17	1.04	0.314	0.35
	Post	10.13 (3.80)	8.28 (3.44)				
FSFI pain	Pre	6.38 (4.05)	5.76 (4.18)	8.86	1.15	0.291	0.37
	Post	6.80 (4.94)	4.79 (5.08)				
FSDS-R	Pre	31.00 (11.64)	33.81 (8.55)	20.44	1.19	0.283	0.37
	Post	27.37 (12.52)	32.30 (9.24)				
CPAQ	Pre	65.31 (16.62)	71.95 (15.75)	686.03	9.80	0.004	1.07
	Post	78.85 (19.22)	73.20 (19.95)				
PCS	Pre	21.13 (8.29)	21.38 (8.30)	115.62	5.20	0.029	0.78
	Post	16.90 (9.45)	22.20 (10.17)				
HADS-A	Pre	9.25 (4.30)	8.43 (4.90)	12.20	3.82	0.059	0.67
	Post	7.05 (4.11)	7.87 (5.06)				
HADS-D	Pre	5.25 (4.33)	5.14 (3.37)	5.38	1.70	0.201	0.45
	Post	3.23 (3.52)	4.21 (3.27)				
SWLS	Pre	22.75 (7.34)	26.14 (5.55)	51.66	11.99	0.001	1.18
	Post	24.62 (7.87)	24.64 (6.43)				
rDAS ^a	Pre	50.33 (6.53)	49.93 (6.54)	6.28	0.675	0.418	0.31
	Post	49.74 (5.84)	50.63 (6.64)				

ANOVA. Time \times group interaction effects. ^an=15 in ACT and n=15 in control group.

we achieved the target completion rate. Even so, there is room for improvement and we could consider ways to increase engagement with the treatment content before a larger trial. We demonstrated good retention in trial, 77 %, and little missing data overall. The attrition rate in this study is similar or lower than what has been reported in previous trials [27–29]. Importantly, most attrition occurred before the start of treatment, suggesting that dropping out was not a reaction to the treatment itself.

Receiving ACT was associated with improvements in sexual satisfaction and pain as compared to the waitlist control condition. The effect of ACT on sexual satisfaction was small, which is in line with the magnitude of the effects of cognitive behaviour therapies, as reported by Brotto et al. [5] in a recent RCT. However, Brotto et al. [5] reported larger improvements in sexual distress than we found in this study. Effect size estimates also showed moderate to large improvements in anxiety and quality of life, and a small effect on depression and relationship adjustment. Online ACT has been shown to reduce emotional distress in various pain populations [27–29, 31], and the results from this study show that this effect may apply also in PVD. Also consistent with prior findings in the context of chronic pain, online ACT was associated with a large increase in acceptance of pain and a moderate decrease in pain catastrophizing [27]. When the effects of different forms of face-to-face CBT have been examined in the context of vulvodynia, results generally point to improvements in depression, pain acceptance, and pain catastrophizing following treatment [5, 6, 44]. Overall, effect estimates in this study show preliminarily that online ACT may produce similar improvements.

This study is limited by a small sample size, possibly affecting the precision of the effect estimates. This concerns the assessment of relationship adjustment in particular, since participants who reported that they were single at baseline did not respond to the relationship adjustment measure. Further, there is no follow-up data on the participants so medium or long term effects of the treatment, even if preliminary, are unknown. Previous studies have shown further improvements among women with vulvodynia between the end of CBT and follow-up [4, 45]. The results in the present study may have been affected by the use of a passive control condition. This may have decreased recruitment, willingness to be allocated, or retention, making this a conservative test, and increased estimates of effects on outcomes. Larger trials with active control conditions and follow-up assessments are needed for more reliable estimation of the effect of online ACT for vulvodynia. This trial was not preregistered, as the main focus was feasibility outcomes and not estimation of treatment effects. However, the main trial [43] and future effectiveness trials should be preregistered.

From the findings in this study, we conclude that some adjustments to study procedure may be needed before proceeding, but a full-scale trial of online ACT for PVD appears largely feasible. A larger trial may need to expand recruitment methods compared to the single service used here, and additional tailoring of the intervention to the specific characteristics of PVD may improve outcome related to sexual functioning. However, the effect size estimates shown in this study suggest that online ACT is associated with beneficial changes in potential treatment processes, and could potentially increase quality of life and emotional well-being among with PVD. Overall, findings from this study encourages a larger trial designed to determine the effects of ACT for PVD.

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Informed consent: Informed consent has been obtained from all individuals included in this study.

Ethical approval: This research complied with national regulations, institutional policies and is in accordance with the tenets of the Helsinki declaration (as amended in 2013), and has been approved by the Regional Ethical Review Board in Uppsala, Sweden (ID Number 2015/31).

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