Master of public health

Master de santé publique

Use of digital therapies in the support of people with chronic vulvar pain (dyspareunia, vulvodynia and vaginismus): a scoping review.

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Location of the practicum : Vulvae Paris, France

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Academic Advisor : Aymery Constant – EHESP

Plan :

Acknowledgment :

As a continuation of my pharmaceutical studies, I joined the MPH to train in health promotion. The practice of pharmacy and hospital pharmaceutical sciences gave me the desire to actively participate in therapeutic education, awareness, prevention and information of patients and their families. I therefore looked for a field in which I could use my scientific expertise to inform and accompany patients in their care. Sexual health, and more precisely that of people assigned female at birth, is a rapidly expanding medical field that still suffers from ignorance, stigmatization and taboo. During my internship research, I was interested in how I could participate in the promotion of sexual health among people with vulvas. It was therefore a real honor to join Vulvae and to participate in the elaboration of digital therapeutic support programs for people suffering from vulvodynia, vaginismus and other vulvar pathologies to help patients relieve their vulvar pain. My work consists of creating programs in collaboration with midwives, physiotherapists, sophrologists, dermatologists and sex therapists and then following the patients who benefit from this program. I make monthly appointments with the patients in order to receive their feelings and to make sure of the good progress of their accompaniment. I also set up evaluation questionnaires to study different physical and mental health indicators. These questionnaires will eventually allow the evaluation of the effectiveness of the program in relieving chronic vulvar pain. In this context, I have been interested in the management of vulvodynia and vaginismus in order to better understand the needs of patients and the limitations of current protocols. In order to define the interest of the therapeutic support program created by Vulvae, I reviewed the studies about the different care protocols for vulvodynia and vaginismus. More specifically, it seemed important to study the potential interest of digital therapies in the care of patients suffering from vulvodynia, sexual pain or vaginitis.The idea is therefore to describe and synthesize the emerging evidence of the usefulness, effectiveness or interest of digital supports in the accompaniment of patients and to define in which context to use these innovative therapies.

I would like to thank the Vulvae team and especially Paola, the CEO, for trusting me every day to create innovative solutions to improve patient care. I am fortunate to be able to use my pharmaceutical and public health training with great autonomy in order to create an inclusive, caring and committed support that is very important to me. This internship is a real trigger for my desire to invest in access to health and I am grateful for the rewarding and stimulating responsibilities that I have been given. I would also like to thank Manon Le Botlan, a midwifery student and very precious friend, for her unwavering support in the hard work I have been going through these past months and for helping me understand many vulvar health practices. Thank you for continuing to stimulate my desire to engage with vulva people by inspiring me through the realization of your incredible work.

Abstract : Vulvar pain affects 15% of patients assigned women at birth and has an impact on the quality of life. Despite the importance of the problem, genital pelvic pain disorder remains poorly diagnosed and poorly managed. Patients are confronted with a long therapeutic wandering and a lack of consensus regarding the care protocol. The emergence of digital therapies offers hope for improving the overall management and support of patients. This therapeutic strategy would allow for the relief of provoked and spontaneous pain as well as the improvement of vaginal penetration. Studies remain scarce and there is a need to review the emerging evidence on the impact of e-health programs on sexual function.

Background : Vulvodynia and vaginismus are two vulvar pathologies that require therapeutic support. To date, patients are confronted with a lack of knowledge of these pathologies by the medical staff and a lack of consensus in the management. Therapy wandering remains in the order of 5 to 7 years. This scoping review responds to the need to synthesize our knowledge about vulvar pain and their management to identify the interest of digital therapeutics. Vulvar pain affects 15% of women during their lifetime, but this pain remains unrecognized and continues to have a very important impact on many aspects of quality of life. The lack of consideration and management is due to the lack of research. If a multidisciplinary approach seems to be the optimal solution with the best benefits, there is a need for recommendation in the coordination of the different actors. Digital therapies are obvious strategies to organize a global support. This scoping review is dedicated to reviewing studies on digital therapies for vulvar and pelvic-perineal pain in order to provide an overview of the state of research and to highlight the emerging evidence of these new therapies on different sexual health indicators.

Acronyme :

ACT : Acceptance and Commitment Therapy

CBT : cognitive behavioral therapy

FSD : Female sexual dysfunction

GPPD : Genito Pelvic Pain Disorder

DSM : Diagnostic and Statistical Manual of Mental Disorders

EMDR : Eye movement desensitization response

ISSVD : International Society for the Study of Vulvovaginal Disease

JLGTD : Journal of Lower Genital Tract Disease

I. Introduction

1. Epidemiology of sexual pain

15% of women will experience chronic vulvar pain in their lifetime(1), but most of the time the causes remain unknown(2). Women go through an average of 7 years of therapeutic

wandering before receiving appropriate treatment(3). Vulvodynia is therefore "an important and neglected women's health condition"The prevalence rate of vaginismus in a clinical setting "has been estimated as 5% to 17%, and it is believed to be one of the more prevalent female sexual dysfunctions"(4). Directly related to these vulvar pains, we can also refer to dyspareunia as another type of sexual pain. "Dyspareunia is defined as genito-pelvic pain during or immediately after vaginal penetration. This condition(5) affects 7.5% of sexually active women aged 16–74 year"(6).

2. Definition of Vulvodynia and vaginismus

Vulvodynia : Vulvodynia is a chronic vulvar pain with no apparent cause. It has been described in 2003 as "Vulva discomfort without relevant visible findings or a specific, clinically identifiable, neurologic disorder" by the International Society for the Study of
Disease (ISSVD). Vulvodynia is defined as vulvar pain persisting for more than three months without identifiable cause(5). The pain manifests itself in the form of burning, itching, tingling, irritation, pulling etc. but the clinical examination is normal. Vulvodynia may be localized to one area: vestibulodynia, clitoridynia or generalized to the entire vulva. The most frequent form of vulvodynia is the provoked vestibulodynia which concerns, as its name indicates, the vestibule(7). This is the lower area of the vaginal entrance The cause is not identified and is currently considered to be a pain message disorder. The pain can be triggered by contact or spontaneously. The diagnosis is made by excluding another pathology that could explain the pain.

Vaginismus : Vaginismus is the involuntary and uncontrolled contraction of the perineum that surrounds the vagina(8). This prevents penetration or makes it very painful. There is a primary vaginismus, which means that it is present from the beginning of sexual life, or a secondary vaginismus, which means that it develops after the first sexual relations. Vaginismus can be total with no penetration possible or partial and then allowing penetration of small diameters: tampons, fingers etc. "Vaginismus is thought to be one of the most common female psychosexual dysfunctions"

There is an overlap between spontaneous or provoked vulvar pain, vaginismus, pelvic-perineal pain and pain during penetration also called dyspareunia. The diagnoses are sometimes related and the management can be based on the same therapies and health actors. In addition to pain, other symptoms, affecting sexual health, are associated with vaginismus and vulvodynia : decreased sexual desire, lack of lubrication, sexual anxiety, decreased sexual fulfillment.

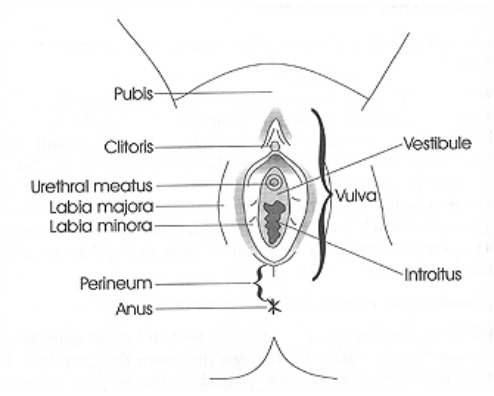

Figure 1 : The Interstitial Cystitis Survival Guide by Robert Moldwin, MD, New Harbinger Publications, Inc. © 2000.

According to the World Health Organization (WHO) definition, sexual health is a group of biological, emotional, intellectual and social aspects of sexual life, essential for positive personality development, communication skills and love. Sexual dysfunction is a term encompassing the various vulvar pains, it is a sexual health related issues that therefore requires solutions to ensure access sexual health care

3. Etiology of vulvodynia and vaginismus

Vulvodynia and vaginismus are consequences of the intertwining of physical and psychological causes. Vulvodynia is now considered as a multifactorial disorder with no one proven etiology. Studies puted in evidence a wide range of interdependent patho-physiological, psychological, social, cultural, and relational
factors as well as critical life events

3.1 Physical causes of vulvar pain.

First we can address **perineum hypertonia.** It is an excessive, constant and involuntary contraction of the superficial muscles of the pelvic floor. This hypertonicity can create spontaneous pain as well as provoked pain, for example, during sexual intercourse with penetration. In practice, this hypertonicity is common and can be both a cause and a consequence of vulvar pain. Indeed, the pain can be the result of this contraction or the pain can trigger this contraction. This is referred to as a **vicious circle of pain** : pain leads to pelvic contraction, which in turn leads to pain. Then, we can highlight persistent **postpartum pain**. Again, the perineum is involved. The aftermath of childbirth can be accompanied by physical difficulties and pain due to the healing process. These pains can generate a hypercontraction of the perineum and maintain the pain. In the presence or absence of pain, a check-up with a midwife or a physiotherapist is recommended in order to determine the appropriate rehabilitation to be implemented. Persistent pain after three months postpartum

is actually abnormal and should be investigated. Other physical **traumas of the pelvis and surrounding areas** are also causes of vulvar pain. Traumas can destabilize the entire bone, muscle and ligament structure. In rehabilitation, tension in the perineum may develop in order to maintain stability.

As we have just seen with these three causes of vulvar pain, the perineum plays an undeniable role in the occurrence of pain. “Vulvodynia has been associated with dysfunction of the pelvic floor muscles, such as hyperactivity, increased pelvic floor tone at rest, deficits in muscle control, and the presence of myofascial trigger points.” Perineal care is therefore essential in the management of pain.

However, other physical factors can be mentioned. We cannot be exhaustive but we can highlight the strong representation of patients who have had **urinary tract infections, vaginosis and recurrent mycosis.** Vaginal infections cause pain: burning, irritation, itching, etc. These infections require treatments to eliminate the pathogen, but these can be drying and irritating. The vaginal bacterial flora is altered following an infection and its treatment and the vulva is then more vulnerable to other pathogens and is more sensitive to irritation. It is common for women to experience recurrent episodes and relapses of infection. A special case is misdiagnosis. Vaginal swabs are not systematically taken to check for the presence of a pathogen. Symptoms are not always the result of the presence of a pathogen. However, in current practice, antimycotics are widely prescribed and dispensed. Patients with vulvar pain often end up applying antimycotics without having a mycosis. This application results in irritation, vaginal dryness, and alteration of the vaginal flora. This is sometimes the beginning of chronic vulvar pain.

Dermatological pathologies are also a common cause of genital symptoms. We can cite the vulvar psoriasis which in addition to itching and burning, are manifested by pink patches in relief. The vulvar eczema is also a dermatitis that causes skin manifestations less delimited. Finally, lichen sclerosus is a pathology that is still unknown to the general public and is characterized by the progressive destruction of the relief of the vulva. The genital lips are then blunted and the mucous membrane can take a pearly color. These skin affections require the implementation of treatment to limit the outbreaks and the evolution. In this context of irritations, chronic pain may set in and require treatment. Vulvar pain can also be secondary to **chronic pathologies** such endometriosis, **fibromyalgia**, **IBD** etc. Chronic diseases have genital symptoms. Endometriosis causes dyspareunia, i.e. pain during penetration, which can develop into vaginismus or vulvodynia. Endometriosis and fibromyalgia can also be the cause of neuropathic pain due to damage to nerves that transmit continuous painful information even in the absence of painful stimuli. When this damage concerns a nerve innervating the perineum, it leads to the development of vulvar

pain or perineal hyperalgesia. Multiple pathologies can be involved in these vulvar pains but we cannot detail them in this paper.

Finally, it is impossible not to raise the subject of **sexual trauma and excisions.** Sexual assault and genital mutilation have physical and psychological consequences. They are therefore intersectional causes. First of all, sexual violence involves physical trauma and pain. Scarring and changes in the appearance of the vulva can cause perineal tension and the appearance of vulvodynia.Sexual and genital violence also has important psychological repercussions and can lead to physical manifestations. Pelvic hypertonicity is one of the symptoms that can be found in people who have been abused. Exposure, touching, verbal and physical aggression, rape during childhood, adolescence or adulthood can lead to short or long term pelvic perineal pain which can cause muscle tension. It is also violence that has psychological consequences and alters the relationship with the vulva. It is therefore a favorable ground for the development of perineal hypertonia. This violence also induces an important defense reaction at the origin of a muscular contraction of closing. When the muscle exceeds its capacity of contraction, it can remain frozen sometimes indefinitely if it is not treated.

3.2 Psychological causes of vulvar pain:

First, phobia, anxiety and depressive disorders are involved in the occurence of vulvar pain.Generally, states of stress and anxiety are expressed by a tendency to "close one's openings" and so the contraction of the perineum makes it possible to close the orifices. Relaxation will therefore be a key element in the treatment. These are protective and coping reactions. Other factors contributing to vulvar pain are strong taboo, strict or religious education. The taboo of sexuality and the genital area or the negative descriptions of the vulva (dirty, forbidden, ugly, vulgar, disgusting etc) can be at the origin of a misunderstanding of anatomy. A strict, religious, very pudish education can nourish false beliefs about penetration and reenforce a sexual fear at the origin of a pelvic contraction. These factors are directly linked to the **lack of knowledge of vulvar and pelvic anatomy.** This ignorance is common and it is due to a lack of correct representation of the vulvar anatomy in schoolbooks and even science books. This lack of correct information leads to a poor understanding of the functioning of one's own genital apparatus. This wastes time for many patients, who postpone the moment of the consultation by simple incomprehension of their symptoms Finally, a large number of people with vulvar pain are also victims of **post-traumatic stress disorder.** It is often encountered following sexual and gynecological violence. Patients may sometimes not be aware of having experienced these traumas, which will then translate into physical symptoms : spontaneous or provoked vulvar pain. This is a mechanism for locking the body and putting the perineal zone under tension. Sometimes

these post-traumatic stresses develop following other traumas such as physical accidents, emotional shocks etc.

Explanation of the vicious circle of pain : The apprehension of penetration or global anxiety can generate involuntary contractions of the perineum which can provoke provoked or spontaneous pain. This pain will then reinforce the anxiety and thus the perineal tensions. It is necessary to stop this vicious circle in order to reduce the pain and regain vulval comfort.

Vulvar pain treatment must therefore be multidisciplinary and involve different health actors and therapeutic strategies. The objective is to take into consideration the patient's globality and to provide her with psychological support, physical rehabilitation associated, educational therapy and if necessary with drug treatments.

4. Present impact of vulvodynia in patient life (9)

Chronic vulvar pain has a significant impact on the quality of life by being a cause of daily suffering. “Genito pelvic pain/ penetration disorder has been shown to have a negative effect on the women’s overall quality of life, with 60% of women reporting that the disorder compromised their ability to enjoy life“. These pains are still taboo and can lead to a feeling of **loneliness**, **guilt** and **shame** for women who do not dare to talk about it to their entourage or their partner. These pains strongly affect self-esteem and can be at the origin of a feeling of failure. It is also an **obstacle to sexual fulfillmen**t, which is one of the indicators taken into account in the definition of health by the WHO.Vulvar pain invites itself into intimacy and threatens sentimental relationships. “Vulvodynia has a negative impact in women's well-being and psychosexual function”. (10) The organization of multiple and often **expensive** consultations is also an important burden that **consumes time and energy** and can interfere with a life composed of social, family and professional activities. “The majority of women with GPPPD do not receive appropriate treatment, which is, alongside the burden for the individual and partner, also associated with economic consequences, such as increased direct health costs including office visits, hospitalization, and medication”. The impact of vulvar pain is global and affects different aspects of physical and mental well-being. “The burden of suffering associated with GPPPD and linked conditions such as vulvodynia and provoked vestibulodynia is high as symptoms have a detrimental impact on physiological and psychological health, and relational well-being”.(11) Vulvodynia is also a risk factor for mental disorders and “it has been linked to depression and anxiety disorder”. Vulvar pain and sexual disorders impair personal growth by contributing "to low self-esteem and feelings of femininity and are associated with negative body and genital images".Vulvar pain and penetration problems are also at the origin of difficulties in conceiving and are therefore causes of infertility. This fertility disorder impacts self-esteem and relationships : “It can pose

a considerable burden on a couples' relationship, especially if they would like to have children" (12).

5. Historical and social context of the sexual pain care

To better understand the gaps in the management of vulvar pathologies, it is important to put vulvar health in its historical and social context. Diagnoses of sexual problems exist in social context and it is important to understand the historical heritage and social factors that still influence care today.

5.1 The treatment of sexual pain in history.

For centuries, sexual pain was attributed to psychiatric disorders, and conversely, psychiatric disorders were attributed to dysfunction of the female genitalia. Diagnoses such as hysteria were found as early as the nineteenth century, and the work of the famous psychoanalyst Freud was part of this belief(13). During the 1950s, the psychiatric treatment of female sexuality continued with the appearance of various diagnoses as nymphomania. The use of medical treatments such as neuroleptics and anticonvulsants became more widespread. For women suffering from sexual pain or not being able to achieve pleasure through penetration, practitioners speak of frigidity. The treatment was for a long time only based on psychology, psychoanalysis and psychiatry. The work of Masters and Johnson is famous and led to the creation of a model " called the Human Sexual Response Cycle". Based on this cycle, they were able to facilitate the diagnosis of various sexual dysfunctions. This is the emergence of a new sex therapy. In 1970 the publication of their text "Human sexual inadequacy" identified three female sexual dysfunctions: dyspareunia, vaginismus and anorgasmia. The approach of this sex therapy is based on the accompaniment of couples with daily exercises to be carried out in order to progressively recover sexual pleasure. Their protocol for the treatment of vaginismus is based on their understanding of the implication of psychological and physical causes. They have therefore taken into account these different factors as a "combination of physical trauma to the genitals plus ignorance and justifiable fear of pain create the perfect constellation for the development of vaginismus". They recommended pelvic contraction and relaxation exercises, the use of vaginal dilators of different diameters and supplemented these physical exercises with sex education and therapy sessions. It is important to emphasize that their indicators of success do not include the evaluation of sexual satsifaction, but only the possibility of obtaining penetration. It was not until the feminist wave of the 70's that the right to female sexual pleasure was gradually taken into account. The importance of self-knowledge and anatomy starts to emerge and liberates women from their passive roles in sexuality. This allows them to understand their own

dysfunctions and to participate a little more in their care. In the 1990s, the inclusion of vulvar pain in the DSM (Diagnostic and Statistical Manual of Mental Disorders) was discussed. The recommendations of diagnosis based on the consideration of different physical and mental factors and multidisciplinary management began to emerge. Until then vulvodynia and vaginismus were not treated as a medical problem but as a sexual-mental disorder. In 2013 the classification changes and vulvodynia and vaginismus are grouped under the name of Genito-Pelvic Pain/Penetration Disorder (GPPPD). These sexual pains have progressively left the field of psychiatry to become, at least in theory, physical health issues. From now on, the diagnosis of vulvodynia or vaginismus is made primarily by a physician and may involve therapists.

5.2 The impact of gender stereotypes on the treatment of sexual pain

“Only 60% of women who report chronic vulvar pain seek treatment, and approximately half of those women never receive a diagnosis” (5). This long therapeutic wandering can be explained in part by the influence of gender stereotypes for decades at each stage of the care of people assigned female at birth. Women's pain, and more specifically, gynecological pain, is widely normalized or even trivialized. The experience of the female cycle, pregnancy, childbirth and postpartum are collectively associated with pain and suffering. This partly explains the lack of consideration for gynecological pain and why women face long years of therapeutic wandering before their pain is recognized (14). Gender bias is also a factor in the recognition of women's pathologies. In fact, the female gender is associated with greater sensitivity, fragility and vulnerability(15). This can lead some caregivers to underestimate the importance of the symptoms described by a female patient. Finally, the concept of somatization is also more easily applied in the interpretation of a patient's symptoms. Somatization is based on the explanation of a symptom by an emotion or a psychological disorder. It is in this context that women's pain is not taken seriously by health care providers. This reinforces the lack of trust, or even distrust, in the health care personnel and is a cause of loss of time in the treatment.

6. Available treatment of sexual pain nowadays

The treatment of vulvar pathologies remains very heterogeneous and there are great disparities between patients in terms of access to treatment and care. “Health care professionals not standardly inquiring about sexual difficulties in routine care visits due to feelings of inadequacy or embarrassment or due to a lack of training, knowledge, or time”(11). The different therapeutic strategies are based on physical or psychological treatments and can be combined in the treatment process.

6.1 Physical care

The physical care techniques are based on the one hand on the realization of massage / self-massage of the perineum and exercises of perineal rehabilitation. Contrary to the most popular rehabilitation, which can be found in case of postpartum or in prevention of prolapse (organs descent), the rehabiliation in a context of sexual pain is based on relaxation. This is a relaxation rehabilitation that aims to relieve tension and regain flexibility in order to reduce pain and gradually allow penetration (16). This rehabilitation is learned from physiotherapists and midwives and can then be reproduced independently. Various prospective and retrospective studies have proven the effectiveness of pelvic floor therapy in the relief of pelvic hypertonicity and dyspareunia. In physical therapies, we include surgical interventions**.** Vestibulectomy is one of the best studied approaches to the treatment of vulvodynia. It consists of the removal of the painful part: the vestibule (fork-shaped area at the entrance to the vagina). This is an invasive treatment that is offered after several lines of treatment have been tried.

6.2 Psychological care

Psychotherapy and sex therapy are widely recommended, different therapies can be used such as EMDR or Cognitive Behavioral Therapies (CBT). In addition to this psychological support, alternative medicine can be used to relax and gain self-confidence such as sophrology, hypnosis, acupuncture or breathing exercises “an array of technical interventions known to effectively treat male and female sexual dysfunctions” (17).

6.3 Prescribed drug treatment

Treatments can be local with a topical application or oral treatments. Pain is alleviated by prescribing lidocaine-based anesthetic cream. The application of the cream is intended for the painful area and can be used several times a day for spontaneous pain or before and after a gynecological examination or sexual intercourse. In some cases, especially in situations of neuropathic pain, other drug treatments may be prescribed. These include tricyclic antidepressant treatments such as amitriptyline and anticonvulsants treatments such as gabapentin or clonazepam. These are second-line treatments used when first line analgesics fail. The use of anticonvulsivant molecules often occurs when neuropathic pain is suspected.

There are different therapies that can be used simultaneously to address the different factors involved in vulvar pain. However, this requires coordination of care in a multidisciplinary approach.

7. Barriers to the implementation of multidisciplinary care

The difficulty lies in the organization and especially the accessibility of this care. Patients are in a state of diagnostic wandering and have difficulty accessing competent specialists in their pathologies. Once the diagnosis is made, one limitation is the lack of official recommendations on the management of vulvar pain and vaginismus. Thus, gynecologists and midwives all have their own protocol and there is great heterogeneity between patients. Another limitation of care is the frequent inability to provide continuous care. Consultations cannot be regular and long term, but the effectiveness of therapies depends on regular care and personalized support. Delays in treatment slow down progress towards pain relief and can even be the cause of relapses. It is also a factor of discouragement and a decrease in patient compliance, which then leads to the patient leaving the care program. Lack of sexual and therapeutic education about the anatomy of the female genital tract prevents patients from becoming active in their care(18). They are then dependent on the caregivers and feel passive and powerless in their care. A shortage of practitioners unevenly distributed over the territory reinforces the difficulty of accessing effective, complete and regular treatment. “the care available may vary depending on local resources”(19) and is the source of inequality of access. Also, these multiple treatments are very costly and many women do not have the necessary budget to set up their care.

Also, there are frequent errors of care due to the lack of knowledge of vulvar pathology by the practitioners themselves. The frequent misuse of antimycotics in the face of symptoms of vulvodynia is a factor that aggravates the pain. These diagnostic errors are common and represent a waste of time and are a cause of aggravation of symptoms. Impact of chronic vulvar pain. There is therefore a real need to create consensus for the diagnosis and care of chronic vulvar pain in order to set up an accessible, effective and equal support. The challenge is here to define the specific needs of the patient and to adapt the care

8. Emerging therapies

Digital media are gradually being democratized to improve patient follow-up, to allow them to actively participate in their care and also to try to reduce treatment gaps. Most of these digital supports are intended to complement medical and paramedical care in order to continue the follow-up and support between consultations. “Internet-based interventions can be one strategy to address some of the limitations of traditional psychological interven-tions with regard to limited availability, high threshold, and costs “. “New technologies also present sex therapy with new modes of treatment delivery.”

Given the reality of daily life for people with chronic vulvar pain, the need for investigation of emerging therapies seems obvious. In order to combine the different treatments necessary

for the global management of vulvar pain and to reach a large public, digital therapies are at the heart of the tracks to be developed to improve care. In order to bring everything together in terms of multidisciplinarity and accessibility, digital therapies seem to have an interesting benefit-cost balance. We have therefore chosen to focus on these digital therapies in order to draw up the emerging evidence of their interest for patients.

9. Research question

The research question is the following :

What are the interests of digital therapeutics based on multidisciplinary treatment and self guided care, in the management of vulvodynia and vaginismus ?

10. Objectives of the present study

The objective of this paper is to better understand the interest of digital therapies for the care and support of people with chronic vulvar pain: vulvodynia and vaginismus. The primary objective is therefore to study and identify the available emerging evidence of the value of digital therapies in the support of people with vulvar pain. The secondary objectives are multiple. The subsidiary objectives of this study are to identify the knowledge gaps around vulvar pathologies and to understand how internet-based interventions could contribute to closing treatment gaps. This research also makes it possible to highlight the need to evaluate digital therapies in order to propose recommendations for their use. Finally, this scoping review aims to establish early recommendations for good practice in the management of vulvar pain and the indication of digital therapies in the light of available evidence.

III. Method

In order to meet the study objectives, a scoping review was conducted from april to july 2022. This scoping review is based on chapter 11 of the JBI manual for evidence synthesis. (20)

1. Scoping method

1.1 Protocol and registration

Following JBI's recommendation, the objectives, the different inclusion and exclusion criteria and the method were set in advance. This qualitative analysis draws on a comprehensive review of the literature to examine the emerging evidence for the value of digital therapies in supporting people with vulvar and sexual pain.

1.2 Rationale

The choice to carry out a scoping review was made in order to review the literature to determine the available digital therapies, the aim being to then list these DTx to highlight their relevance and effectiveness. Also, the interest of the scoping review is to list the different indicators allowing to evaluate the impact of the digital therapy on the quality of life of the patients. The extraction of these indicators would then be usable to create a protocol of evaluation of the whole of the therapies dedicated to the chronic vulvar pain.

1.3 Inclusion and exclusion criteria

Digital therapeutics : The studies included in the scoping review are digital training programs, digital therapies or online coaching for people with vulvar pain, vaginismus and female sexual dysfunction. These programs should be multidisciplinary and cross-cutting, including both physical and psychological therapy, and allow people to provide self-care. These studies must include a minimum of 50 patients of the treatment protocol. Papers on digital programs focusing on sexual dysfunction including both sexes and therefore including male sexual dysfunction were excluded from the scoping review in order to focus on female body issues.

Population based sample : The studies included in the scoping review were on population samples was composed of heterosexual women committed in a relationships and suffering with either: vaginismus, sexual dysfunction, chronic pelvic pain, vulvodynia.

2. Type of studies and methodology

This scoping review includes prospective studies using per protocol or intention to treat analysis. In terms of date of publication only studies published after 2005 were included in the review. During the search, given the limited resources found, we decided to also include ongoing studies. Also, we decided not to exclude studies on sexual pain or sexual dysfunction due to other pathologies.

3. Search strategy

3.1 Scoping protocole

In a first step we proceeded to the exploration of the literature available on pubmed, journal of lower tract disease, science direct during april, may and june 2022. We first used only Pubmed and journal of lower genital tract disease to identify resources availble on digital therapeutic for sexual pain.The objective was first to define whether a scoping review was possible by studying the literature available to date. This first review used the presence of key words in the title and abstract of the papers. The analysis of the subject and the type of

studies carried out was then carried out in order to define the consistency with the current scoping review.

3.2 Keywords use

In this scoping review we used these keywords : vulvodynia, vaginismus, vulvar pathologies, vaginismus management, vulvar pain management, dyspareunia, internet based treatment, pelvic function, sextherapy, pelvic pain. Studies were selected by the main author.

3.3 Data extraction

Our work then consisted of data extraction to identify emerging evidence of the value of DTX in the management of vaginismus and vulvodynia. This data extraction was conducted on 5 studies and the data were collected in an excel table in order to be able to compare the data between the studies. Several rounds of reading and data extraction were performed during the study as the importance of certain indicators became apparent. In parallel, the scoping review allowed us to study secondary criteria such as gaps in terms of diagnosis and management and the interest of the digital supports to reduce these gaps. Finally, the interpretation of the data allowed us to propose recommendations for the integration of DTX in the management of patients with vaginismus and/or vulvodynia.

3.4 Critical evaluation and assessment of the included studies :

Given the nature of the scoping review, no critical assessment of the studies in terms of bias or study quality was conducted

III. Results

1. Search results

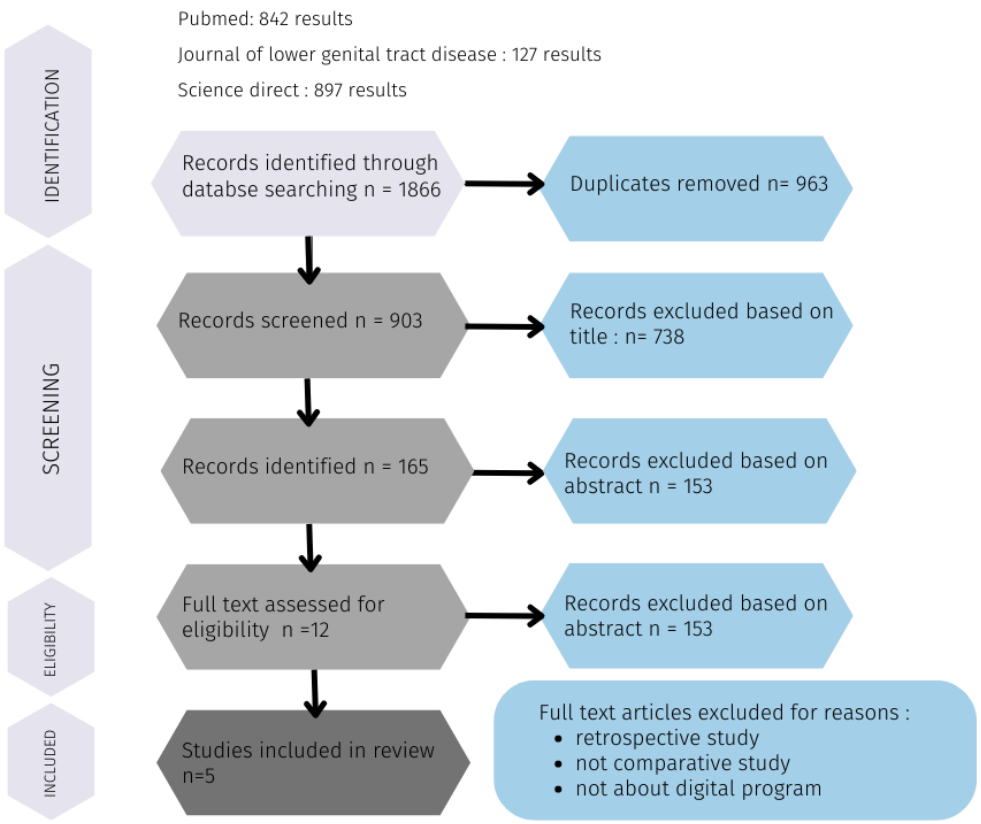

Figure 2 : PRISMA-ScR flowchart illustrating the process of literature search and extraction of studies meeting the inclusion criteria

2. Review finds :

2.1 Type of DTx available

A review of the various studies on the subject of digital therapies in the treatment of sexual pain will allow us to take stock of what is available to date. We can then identify different types of digital therapies that form the landscape of vulvar pain treatment. The first type of digital therapy that we can describe thanks to the work of Zarski et al is a program including psychological techniques such as psychoeducation, self-awareness and relaxation as well as physical therapy techniques based on perineal re-education exercises of relaxation and progressive exposure to the insertion of dilators or fingers. The psycho-corporal techniques are therefore the core of this intervention which is studied in the context of care for vaginismus and then in a second study in genito-pelvic pain in general. Relaxation techniques and deconstruction of negative thoughts allow the body to be put in optimal conditions to perform physical exercises. It is a treatment based on CBT presented to patients in the form of text, video, audio and quizzes. These two studies integrate the participation of the partner in the sensate focus exercises. The goal is to improve the establishment of intimacy and the exploration of the passive and active roles of each. These programs are designed for couples and include exercises for the male partner. This program

studied by Zarski et al in the context of vaginismus care and GPPPD care also allows the connection with coaches for support through message exchange. The third paper included from the work of **Hess Hess Engstrom et al** evaluates the effectiveness of a program similar to the two studies presented above. The intervention is a CBT-based program that includes ACT techniques developed for chronic pain and adapted for vulvodynia. The format of this digital therapy is quite similar to the one studied by Zarski et al. The platform provides written files, audio-visual documents and questionnaires to the patients. The different modules are dedicated to information, education, guidance in performing pelvic floor re-education exercises and gradual exposure to dilators or fingers. The program also allows them to get in touch with coaches for an online follow-up. The fourth study **The Effectiveness of an Internet-Based Psychological Treatment Program for Female Sexual Dysfunction** is an evaluation of a psychological intervention in the form of a CBT-based couple program. The program included different modules dedicated to communication skills, sensate focus sessions and unlimited contact with a coach by email exchange. This program does not include explanations of anatomy, physical exercises or progressive exposure to penetration. Finally, the fifth study included in the scoping review evaluates the effectiveness of an internet-based porgram for cancer survivor with sexual dysfunction. This program is based on therapeutic education, self-observation and learning about one's anatomy. The content also includes information about sexuality with the symptoms that patients may experience and possible solutions to use to relieve pain and improve lubrication. Physical therapy is covered with a detailed presentation of pelvic floor rehabilitation exercises with videos from a rehabilitation professional and the use of dilators. There are also contents dedicated to personal well-being and reconciliation with one's image, sexuality and pleasure. These materials are designed to boost self-esteem. This program is therefore in line with the first two programs, combining physical therapy with educational and psychological support. However, its content is adapted to a population that has been affected by breast or gynecological cancer. Also, an important difference of this coaching program is that it includes three in-person follow-up appointments with a therapist. These follow-up appointments were set up for one arm of the study and compared to the arm that only had access to the internet based program. This study therefore has two parallel evaluations. The first one allows to evaluate the impact of the online program on the different indicators of sexual health and quality of life and the second one allows to define the interest of adding barriers with professionals. A third type of digital therapy could be a personalized version of the two types of therapies defined just before. The fifth paper is about a study adapted for a specific disease. We can imagine variations adapted to the pathway, the context and the associated pathologies of each patient

By reviewing these studies, it is possible to differentiate two main types of online interventions: a first category of intervention based on both psychological techniques and physical exercises in a multidisciplinary mind-body approach. The second category that we can highlight is digital therapy based exclusively on psychological techniques for individual and couple use. All of these digital therapies involve online follow-up by a professional health coach: therapist or psychologist.

2.2 Outcome measurement instruments

The review of studies highlighted the use of indicators assessing markers of effectiveness in terms of physical health, mental health, well-being and quality of life. Different self-report questionnaires were used in the studies included in the scoping review. The identification of these indicators and the methods used to evaluate them allow us to draw up recommendations in terms of protocol for the evaluation of online treatments for vulvar pain. These questionnaires allow to establish criteria to evaluate the impact of the interventions on physical, psychological, relational and social indicators. These questionnaires make it possible to obtain a score to compare the various indicators between two groups: one having benefited from the digital intervention and the other without treatment or with another treatment. These questionnaires also make it possible to evaluate the before and after an intervention.

In the five papers under review in this scoping review, the **Female Sexual Function Index (FSFI)**(21) is the questionnaire of choice for assessing primary outcome. It is a self-report instrument for the assessment of female sexual function. It is validated for women with and without chronic conditions such as cancer. Subscales measure sexual desire, arousal, lubrication, orgasm, satisfaction, and pain. The total score reflects both function and satisfaction. “This questionnaire is therefore important in sexology, gynecology, and venereology.” The FSFI questionnaire consists of 19 close-ended questions related to sexual activity within the 4 weeks prior to the examination and includes six domains :
Questions 1-2 : Sexual desire - Questions 3-6 : Sexual arousal - Questions 7-10 : Lubrication - Question 11-13 : Orgasm- Question 14-16 : Satisfaction- Questions 17-19 : Pain. Obtained score can go from 2.0 points to 36.0 points. It is therefore an essential questionnaire in the evaluation of digital therapies. It has the advantage of assessing sexual health by taking into account physical sensations as well as psychological dimensions of sexuality such as desire and sexual well-being. Next, we can classify the questionnaires into different categories. In the first category, there are the questionnaires that are mainly about physical sensation and physical functions. The most obvious and basic score to set up is the **Pain scale** which allows you to evaluate your pain on a scale from 0 to 10. The **Vaginal Penetration**

Cognition Questionnaire (VPCQ) (22) is a valid and reliable brief self-report measure for assessing cognitions regarding vaginal penetration in women with vaginismus or dyspareunia. It is an instrument developed with psychometric properties to be used in research and clinical studies. It is a 40 items questionnaire including 5 subscales regarding cognitions about vaginal penetration: "control cognitions,""catastrophic and pain cognitions,""self-image cognitions,""positive cognitions," and "genital incompatibility cognitions.". The **Sexual Function Scale (SFS)** assesses the influence of childhood, family environment, adolescent experience and current situation on sexual functioning. Three major section : Childhood / Puberty and adolescence / Current attitudes and behavior. Other questionnaires are more focused on the evaluation of psychological state, mental well-being and perception of sexuality. **Fear of sexuality scale (FSS)** or **Fear of intimacy Scale (FIS**) (23) is a 35-item self-evaluation that can determine the level of fear of intimacy that a patient can. The **Beck Anxiety Inventory (BAI)**(24) is a list of 21 anxiety symptoms that can be used to assess psychological status and detect anxiety-depressive disorders. This scale is a self-report measure of anxiety.). **The EuroQol-5-dimension questionnaire (EQ5D)**(25) is an instrument for measuring quality of life and consists of two parts: one about different dimensions of health-related quality of life, and one part with a Visual Analogue Scale where the respondent assesses their overall health status . The fifth study of sexual function in breast and gynecologic cancer survivors uses the **Quality of Life in Adult Cancer Survivors scale (QLACS)**(26). The purpose of this questionnaire is to assess the general well-being of patients after cancer, so it is less specifically related to sexual pain but includes items about sexual health. This score is therefore interesting in the specific context of genital pain resulting from cancer.Finally, in the context of digital interventions for couples, questionnaires to assess the evolution of intimacy between partners have been used in studies. **The Personal Assessment of Intimacy in Relationship Scale (PAIRS)** (27)is a scale assessing intimacy in the relationship and is commonly used in marital research and therapy. It is composed of 36 items and 6 subscale : emotional, social, sexual, intellectual, recreational and conventionality. Also, the **Dyadic coping inventory (DCI)** (28)is an instrument designed to measure perceived communication and dyadic coping (supportive, delegated, negative, and joint) that occurs in close relationships. **The Menopausal Sexual Interest Questionnaire (MSIQ)(29)**, is a 10-item scale with excellent internal consistency and test-retest reliability, with subscales measuring desire, responsiveness (pleasure and orgasm), and satisfaction. This questionnaire is used in the context of medically induced menopause due to hormone therapy for breast or gynecological cancer. The effectiveness of the programs and the physical, psychological and relational benefits are not the only criteria for defining a suitable program. The patient experience and satisfaction are also necessarily to be studied in order to define the areas of improvement to continue to improve digital

therapies. Satisfaction has a direct impact on the therapeutic alliance between the patient and the health care professional and will have a significant impact on compliance with care. The **Patient experience questionnaire (PEQ)(30)** emphasizes what patients value the most, i.e. interaction, emotions and outcome. This tool makes it possible to obtain feedback on the service provided by an intervention. Each item is evaluated with a 5-point scale. **The Client satisfaction questionnaire CSQ-8 (31)**is a validated psychiatric tool to assess the subjective experience of the patient.

Title and reference	**Internet-Based Guided Self-Help for Vaginal Penetration Difficulties: Results of a Randomized Controlled Pilot Trial.** Zarski, Anna-Carlotta; Berking, Matthias; Fackiner, Christina; Rosenau, Christian; Ebert, David Daniel (2017). The Journal of Sexual Medicine https://pubmed.ncbi.nlm.nih.gov/28161080/	**"Efficacy of Internet-Based Guided Treatment for Genito-Pelvic Pain/Penetration Disorder: Rationale, Treatment Protocol, and Design of a Randomized Controlled Trial."** Zarski, Anna-Carlotta et al. Frontiers in psychiatry vol. 8 260. 22 Jan. 2018 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5786827/	**Internet-based treatment for vulvodynia (EMBLA) - A randomised controlled study.** Hess Engström AH, Kullinger M, Jawad I, et al. Internet Interv. 2021;25:100396. Published 2021 Apr 20. https://www.researchgate.net/publication/357391035_Internet-based_Treatment_for_Vulvodynia_EMBLA_-_A_Randomized_Controlled_Study	**The Effectiveness of an Internet-Based Psychological Treatment Program for Female Sexual Dysfunction** Lisa M. Jones, DPsych (Clinical) and Marita P. McCabe, PhD School of Psychology, Deakin University, Melbourne, Vic., Australia	**Efficacy Trial of An Internet-Based Intervention for Cancer-Related Female Sexual Dysfunction** Schover LR, Yuan Y, Fellman BM, Odensky E, Lewis PE, Martinetti P.
Type of study	RCT prospective : 6 month follow up + intention to treat analyse	RCT prospective : 6 month follow up + intention to treat analyse	Multi-centre RCT prospective : 9 month follow up + intention-to-treat and also per protocol approaches	RCT prospective	Randomized trial Prospective study during 12 week treatment
Aims	Compare participants using the internet-based guided self-help training Vaginismus-Free with those assigned to a waiting control group	investigate the efficacy of a newly developed Internet-based guided self-help intervention for GPPPD.	Provide a novel and better understanding regarding the treatment of vulvodynia and the role of internet-based treatment as a complement to standard care for women suffering from vulvodynia	Evaluate an Internet-based psychological treatment program for FSD	Compare the effect off self help digital interventionby comparing self help group to counseled group
Study sample	77 heterosexual women with vaginismus (6month at least with no penetration)	200 women with GPPD	99 heterosexual women with vulvodynia	39 heterosexual women with fuction sexual disorder FSD engaged in a stable relation ship + their partners	58 women survivor of breast / gynecological cancer
Type of digital interventions	CBT based multidisciplinary program + ACT component 6 week treatment 30 minutes / day 6 modules Support : videos, audiofiles, self assessment Online follow up by e coach mindfluness + pelvic exercice+ body exposure exercise with dilatators/fingers	CBT based multidisciplinary program + ACT component 6 week treatment 30 minutes /day 6 modules Support : videos, audiofiles, self assessment Online follow up by e coach mindfluness + pelvic exercice+ body exposure exercise with dilatators/fingers	ACT/ CBT based program 8 to 16 weeks program 1 to 2 session of 45-60 min/ week Education, relaxation, cognitive restructuring, body exposure fingers and dilators, preparation for sexual intercourse Support: text, videos Online follow-up by coach	**"Revive" program**: internet based CBT program for women and partners: 10 weeks program - 5 modules only psychological approach program supports : text files follow up by therapist online	CBT based program + multidiscplinary techniques 12 week programm Educational, psychological and physical coaching +/- 3 in person appointments with counselor for one arm (36 patients)
Inclusion criteria	- No penetration possible in the last 6 month - No higher than 1 point on the PEQ (questionnaire - In a heterosexual relationship for at least 3 months - Internet access - Sufficient wrtient/ reading skills in german - Willing to give informed consent	- No penetration possible in the last 6 month - No higher than 1 point on the PEQ (questionnaire - +18 years old - In a heterosexual relationship or heterosexual partner - Internet access - Sufficient writing/ reading skills in german - Willing to give informed consent	- Symptoms of vulvodynia for at least 6 months, and confirmation of the medical diagnosis at the gynaecologist's appointment after study recruitment from waiting lists for clinical treatment, or by the woman herself following study recruitment through social media. - Access to a computer with internet connection. - Age of ≥18 years. - A Swedish personal identification number for access to the treatment platform.	- Currently experiencing FSD - In a stable hetero- sexual relationship - Over 18 years of age - Have regular Internet access; - Willing to complete three outcome questionnaire measures at different time points - Willingness and motivation from partners to participate in treatment - Commitment to at least 3 hours a week, for a minimum of 10 weeks to complete the treatment program.	- Women from tumor registrary - survivros of breast cancer or gynecological cancer - 1 to 7 years post diagnosed of localized breast/ gynecological caner - No active treatment other than homing therapy - Committed in a sexual relationship for at least 6 months - Partners willing to participate to the program - close enough to attend in person counseling - Writing/reading skill in English - Internet access
Exclusion criteria	- Previous PTSD - current/ previous psychosis or disossociative symptoms - current substance abuse or dependency - Current depression or bipolar disorder - current treatment fr vaginismus	- Previous PTSD - current/ previous psychosis or dissociative symptoms - Current substance abuse or dependency - Current depression or bipolar disorder - current treatment for GPPPD	- Unclear diagnosis at the screening interview. - Ongoing examination/treatment related to vulvodynia. - Lack of fluency in Swedish, since the treatment is delivered in Swedish. - Severe, acute, or untreated mental illness or substance abuse.	- current other psychological treatment - current other medical treatment for FSD	- Ongoing cancer treatment - FSFI > 26,5 not scored as dysfunctional
Main outcome	Sucessful sexual intercourse (with penis insertion)	Sucessful sexual intercourse (with penis insertion)	Provoked vulvar pain	Sexual function evaluated by FSFI score : sexual desire, sexual arousal, lubrication, sexual satisfaction, orgasm, genital pain	Sexual function and sexual satisfaction
Secondary outcomes	Non-intercourse penetration Fear of coitus Sexual functioning Dyadic coping	Non-intercourse penetration Sexual functioning Dyadic stress coping Fear of sexuality and negative penetration-related cognitions.	Depression/ Anxiety Sexual function Quality of life.		Menopausal sexual interest emotionnal distress Quality of life
Data collection / measurement instrument : Primary outcome :	The seven-item **PEQ** will be used as a primary outcome measure: PEQ online or phone assessment. Questionnaire likert scale 0 = not attempted; 1 =attempted, but unsuccessful; 2 =attempted and sometimes successful; 3 = attempted and always successful = SCORE	The seven-item **PEQ** will be used as a primary outcome measure: PEQ online or phone assesment. Questionnaire likert scale 0 = not attempted; 1 =attempted, but unsuccessful; 2 =attempted and sometimes successful; 3 = attempted and always successful = SCORE	Self-reported pain : 0 ("no pain") and 10 (" worst possible pain") during vaginal intercourse + tampon test.	- FSFI = self report - Sexual Function Scale (SFS) - The Personal Assessment of Intimacy in Relationships (PAIR) Scale : self report questionnaire t	FSFI : Self report
Data collection / measurement instrument: Secondary outcomes	- PEQ 6 last items : Non coital penetration mesured - Fear of sexuality scale : 5 items Likert scale (1 = never to 5 = always) - Female Sexual Function Index (FSFI): 0-5 - Dyadic Coping Inventory : 5 pont scale 0 -4 - Client Satisfaction Questionnaire : CSQ-8 validated eight-item instrument with high internal consistency	- PEQ 6 last items : Non coital penetration mesured - Fear of sexuality scale : 5 items Likert scale (1 = never to 5 = always) - Female Sexual Function Index (FSFI): 0-5 - Dyadic Coping Inventory : 5 pont scale 0 -4 - Vaginal Penetration Cognition Questionnaire (VPCQ) self-report instrument 7-point Likert scale - Client Satisfaction Questionnaire : CSQ-8 validated eight-item instrument with high internal consistency	- Chronic pain acceptance questionnaire (CPAQ) self assessment - The Female Sexual Function Index (FSFI) - Female Sexual Distress Scale-Revised (FSDS-R) - Beck Anxiety Inventory (BAI) = score - Satisfaction with Life Scale (SWLS) : 5 items scale	Depression, Anxiety, Stress Scale (DASS21)	- Menopausal Sexual Interest Questionnaire (MSIQ) - Brief Symptom Inventory-18 (BSI-18) assessed emotional distress with a Global Severity Index (GSI) - The Quality of Life in Adult Cancer Survivors (QLACS)
Results in main outcome	**Significant increase in intercourse penetration** from baseline to 6 months	**ANTICIPATED RESULTS :** - increase in the ability to have sexual intercourse - positive cognitions toward vaginal penetration - decrease expected in genito-pelvic pain, fear of pain and penetration, and negative cognitions associated with intercourse and sexuality	- Significant lower pain in intervention group but no significant decrease in term of discomfort/fear at tampon test. - No significant differences in term of pain impact on sexual function	- Significant improvements in sexual function from pretest to posttest in IG - Significant improvements from pretest to posttest in levels of sexual desire - significant difference between the treatment and control groups in the frequency with which their female sexual dysfunction was perceived to be a problem - Significantly improvements in the relationship factors with their partner - No significantly greater improvement from pretest to post- test on any of the individual factors	- Significant increase in sexual function and sexual satisfaction in menopausal women - No difference on the sexual function between patients who had access to the counseling appointment and patients with only the online program.
Results in secondary outcome	- Significant increase between-group effects concerning non-intercourse penetration (self-insertion of a finger or dilator or insertion by the partner) in favor of the IG - Higher scores for self-insertion in IG - Significant decrease in fear of coitus was observed in IG - No significant difference in female sexual function within group and between group		- No significant differences in terms of « sexual activities besides intercourse » and « willingness to perform the tampon test ». - Significant higher pain acceptance and activity anegement in the intervention group - Significant lower pain intensity during intercourse in the intervention group	Improvements in all areas of sexual functioning (sexual desire, arousal, lubrication, orgasm, satis- faction, and pain) were significantly greater among those women who completed the program compared with those who received no treatment.	Significant decrease of emotional distress and significant better ratings of overall quality of life at post treatment

Figure 3 : Table of included studies

2.3. Narrative synthesis of mains outcomes of eligible studies

By studying the scores obtained in these different questionnaires we can have a more precise idea of the interest of the digital therapies studied on the different aspects of sexual well-being and the management of vulvar pain. Thanks to these five studies and the census of the answers to the different questionnaires, we have access to the first results of the impact of these therapies.

A. Physical impact of digital program

Achieving penetrative sex / achieving non-coital penetration :

Overall, studies evaluating the possibility of achieving penetration in a coital or non-coital context tend to show an improvement in the possibility and comfort of penetration. Zarski et al. study(32) among patient suffering from vaginismus found a significantly higher rate of successful penetrative sex during intercourse in the digital program group. Whereas before the procedure, none of the patients had been able to have penetration during sexual intercourse : ”34% of the participants in the IG reported at least at one measurement point that they successfully had sexual intercourse”(32). This same study assessed secondary indicators to complement the study of the impact of this digital follow-up. Among these indicators, the evaluation of the possibility of vaginal penetration outside the context of sexual intercourse (finger, vaginal dilator, speculum, etc.) showed a significant difference in favor of the intervention group benefiting from the program. However, despite significant improvements, the study also highlighted the need to continue to improve penetration to the comfort level of a person without vaginismus during intercourse or vaginal insertion of fingers, dilators etc. The second study by Zarski et al. on patients suffering from GPPPD shows early results in favor of an improvement of vaginal penetration in the intervention group compared to the control group(11). The anticipated results tend to highlight the improvement in the ability to have sexual intercourse with penetration.

Provoked and spontaneous vulvar pain :

Zarski et al. study on GPPPD suffering patients tends to show a decrease in provoked genito-pelvic pain in the group benefiting from the program(11). The EMBLA study by Hess Engstrom et al.(10) conducted on 99 women with provoked vulvar pain showed a significant reduction in pain during sexual intercourse in the intervention group compared to the control group.The study shows a 30% decrease in pain intensity during sexual intercourse but clinical demonstrations are needed to confirm this. This same study showed no significant

difference between the groups in terms of pain experienced with the tampon test (i.e. attempt of non-coital penetration) and the impact of pain on sexual function.

Sexual function : lubrication, sexual satisfaction, orgasm, genital pain.

This indicator refers more generally to physical sensations related to sexuality and includes parameters other than pain or the possibility of penetration. In Jones et al. study of the « Revive » online psychological intervention, FSFI is used to measure the main outcome.(33) The treatment group reported significantly greater improvements in sexual function from pretest to posttest compared with the control group. According to the study by Schover et al., the intervention among people with cancer-related sexual dysfunction significantly improves sexual function.(34) However, over the duration of the study, it did not allow normal FSFI and MSIQ scores to be achieved, and therefore normalization of sexual function.

B. Psychological and wellbeing impact of digital program

Sexual well-being, desire and sexual anxiety :

Zarski et al. work on digital intervention among patients with vaginismus failed to show a significant difference between the groups in terms of fear and anxiety of penetration. However, within-group assessment during the intervention using the Fear of sexuality questionnaire showed a significant decrease in the fear of sexuality between the beginning and end of the program.(32) Also, the second study conducted by Zarski et al. and including more women in the sample is still in progress and significant results are expected.(11) The anticipated results study conducted by Zarski et al. among GPPPD patient tend to show a decrease in sexual anxiety and apprehension of coitus as well as a decrease in negative cognitions associated with intercourse and sexuality. "A decrease is expected in genito-pelvic pain, fear of pain and penetration, and negative cognitions associated with intercourse and sexuality in the IG not in the WCG."(11) Research is therefore needed to evaluate the real effect of digital intervention on the psychological and relational aspects of sexuality in the context of genital and pelvic pain. Hess Engstrom et Al. EMBLA study put in evidence a "significant difference in pain acceptance and activity engagement was found at post-treatment in favor of the intervention group".(10) This is an important argument in the ability to break the vicious circle of pain and the ability to dissociate the genital area from sensations and negative emotions. Also, evaluation of the impact of the *«* Revive » psychological program showed improved sexual satisfaction and increased sexual desire. (33)

Autonomy in the realization of one's own health care and self awareness

The results highlighted by the study of Zarski et al. concerning the improvement in obtaining penetration, among a group of patients suffering from vaginismus, are very interesting when put in relation to the need to overcome the fear of loss of control that is described by patients with vaginismus.(32) Successful penetration during or outside of sexual intercourse is related to the ability to overcome the fear of loss of control. This study then puts into perspective the importance of regaining control in one's own care to improve treatment outcomes. The evaluation of the impact of the psychological support program failed to show an effect on individual psychological effects such as depression, anxiety and stress.(33) The results were not significant, but the trends were in favor of an improvement of these indicators in the intervention group.

Relationships and couple intimacy

The Zarski et al. study on vaginismus showed a significant decrease in delegated dyadic coping. (32) The « Revive » intervention studied by Jones et al seems to be in favor for a better communiction, sexual intimacy and emotional intimacy in the couple relationship. “Relative to the control group, the treatment group reported significantly greater improvements in the relation- ship factors with their partner from pretest to posttest.“ (33)

Quality of life

Avi et al. intervention on people whose vulvar pain is not related to cancer studied by Schover et al showed ” improved ratings of overall quality of life at posttreatment”. (26)

C. Program compliance

Poor compliance is a particular problem addressed by online self-help programs. Follow-up by eCoaches is a major asset for program compliance. Email reminders in the form of notifications of sessions to be carried out and informative content to be consulted is also a beneficial factor for compliance.The two studies conducted by Zarski et al. (11,32) proved an increased adherence in a context of online interventions thanks to the eCoach guidance and the sending of written feedback on completed sessions. According to the EMBLA study (10), these coaches are an added value to the program regardless of their status as health professionals. “Guided internet interventions may facilitate adherence regardless of guidance levels and quality of eCoaches”.

D. Users satisfaction

Zarski et al. study highlight a great patient satisfaction. “Most participants (26 of 35, 75%) were satisfied with the training. Most participants indicated that the quality of the training was high (24 of 35, 68.57%). Likewise, 18 of 35 participants said they had received the kind of

training they wanted (51.43%). Many participants also perceived that their needs had been met (20 of 35, 57.14%) and were satisfied with the support they had received (18 of 35, 51.43%). Most participants indicated that they would use it again should the need arise (27 of 35, 77.14%). More than half the participants reported that the training had helped them deal effectively with their problems (19 of 35, 54.29%), and most participants (27 of 35, 77.14%) would recommend the intervention to a friend."(32)

E. Emerging evidence of the value of a multidisciplinary approach to the management of vulvodynia and vaginismus

As Marta Meana and Sarah Jones describe in the paper "Developments and Trends in Sex Therapy: "the human sexual response involves both mind and body"(35). The different aspects of sexual health therefore seem inseparable and should be addressed in a systemic approach. According to the work of Zarski et al. on patients with vaginismus, relaxation exercise and dilatator exercise were perceived to be the most efficient, this reinforces the idea of a multidisciplinary approach using both a physical and psychological approach. The exercises seem to be complementary and work together. (32) "Due to the biopsychosocial nature of GPPPD, a multidimensional integrative treatment approach is needed that targets not only difficulties with vaginal penetration, pain, anxiety, and muscle tightness associated with sexual intercourse but also sexual satisfaction and couple dynamics." (11)

F. Emerging evidence in term of other advantages of digital therapeutics use :

Digital therapies offer other advantages than their potential efficiency. It would allow better accessibility and would help fight against geographical isolation and medical deserts. According to the Hess Engstrom et al. EMBLA study : "Internet-based treatment would also enable participants from different and often remote geographic areas to receive treatment." (10)Also, it would allow greater flexibility of time with the possibility of following the program from anywhere at any time. It would also be a solution for people who are anxious, fearful of interaction with healthcare providers and would allow them to remain anonymous. Zarski et al. put in evidence the accessibility of DTx : "most participants (87%) sought help for the first time concerning their penetration difficulties, a fact that could indicate that internet-based interventions might be an option for women who might not seek or who do not have access to treatment". This study highlights the need to spread care through technology in order to close the care gap. In fact "internet-based interventions might address a group of patients who would remain untreated otherwise". (32) Finally the study of the utility of the psychological program « Revive » highlights its interest in reaching target populations facing difficulties in accessing care in general. "Internet-based treatment is likely to be of particular benefit to women who have barriers preventing them from attending face-to-face sessions,

such as geographic isolation, financial difficulties, or embarrassment about discussing sexual problems in the presence of a clinician."

G. Emerging evidence of limitations in the use of digital therapies :

Even if digital therapies seem to allow a larger target group to access adapted care, there are still limitations in terms of accessibility. EMBLA study is based on the fact that "most of 97% of the population has access to fast internet" (10) but digital therapies require expensive equipment and easy access to an efficient internet. " More work remains to be done in terms of extending the Internet offerings to larger and more diverse populations of subjects and providing extended follow-up regarding the stability of change". An easier use or an assistance to the use of these supports could be necessary to reach people whose capacity to use online supports is limited: visual handicap, motor handicap, language barrier etc. Another limitation of online programs would be the lack of close accompaniment and the need to acquire autonomy in order to follow the different stages of the interventions. The study by Zarski et al. among women with vaginismus highlights areas for improvement regarding the guidance of patients in the concrete application of advice, especially with regard to maintaining motivation, regularity in care and the management of negative emotions.(11) Some explanations concerning the interest of the exercises were also requested to better put into perspective the usefulness of digital therapy. The use of online platforms may have been a limitation in the effectiveness and compliance of patients. For example, the study among people with cancer-related vulvar pain conducted by Schover et al. showed a need for improvement in the user experience despite good overall satisfaction with the tool. Studies highlight the need to broaden the target patient population by creating programs that are accessible to people who are single or have a sexual orientation other than heterosexual. We can imagine in the light of these papers, the interest of a personalized program according to the patient's profile.

The question of where digital support fits into patient care arises. One of the main concerns is the comparison of the effectiveness of online versus face-to-face training or coaching. Recent meta-analytic studies of online interventions have directly compared digital approaches to face-to-face therapy and found no difference in effectiveness. However, this study tends to support the use of internet interventions as a complement to face-to-face therapy.

Discussion

Our results indicate that studies on digital therapies in the treatment of vulvar pain are scarce, and therapeutic strategies for these chronic pains are poorly documented. While the

trends in the five studies included show encouraging results in terms of improved sexual function on a physical, emotional and relational level, the results also show the absence of a total reversal of symptoms. Digital therapies need to be maintained over a longer period of time, can be improved and require further studies to better evaluate their impact. It would be unrealistic to imagine a total cure after 6 to 12 weeks of treatment, especially in the context of chronic pain that has been present for several years. In view of the different studies included in this scoping review, the programs have been shown to improve symptoms of vulvodynia and vaginismus. The DTx studied in the five papers seem to allow a significant improvement of the symptoms without leading to a complete cure. Longer, more intense programs or including more treatments may be more effective in achieving remission. Digital therapies are promising and require further research to provide better accessibility for people in medical deserts and an alternative in a context of shortage of practitioners, better integration into daily life, greater autonomy and regaining control of one's care path and would be a solution for the implementation of multidisciplinary care. We can highlight a number of limitations concerning Dtx through the review of these papers. Only few studies have applied randomized controlled trial (RCT) design, most of them with only small sample sizes. Also, the studies are not blinded and there is therefore an interviewer bias and a non-negligible detection bias. However, the procedure seems difficult to implement and could be considered in the context of a comparison of two validated digital therapies. To date, given the absence of alternatives, digital therapies cannot be the subject of a randomized double/single blind controlled trial. Another bias that must be addressed is the almost exclusive use of self-report questionnaires. This leads to a bias in the objectivity of the evaluation of the different indicators when one considering the interference of emotions and thoughts in the self-evaluation process. A possible sexual dysfunction of the partner of the person receiving the program is not taken into account in the different studies included. Patients in a relationship may also be confronted with their partner's sexual dysfunction and this should be addressed in digital programs. Regardless of the gender and sex of the partner, the merging of online therapeutic support programs to act on individual and couple criteria could be an option to explore. A major pitfall of the five studies we reviewed appears to be the lack of representativeness of the target population. The work of zarski and l reveals a major recruitment challenge "as the majority may not have contacted a health practitioner before for their sexual dysfunction."From the moment of recruitment, some of the people concerned are difficult to reach, and then during the inclusion and exclusion of participants in the study we can identify various limitations. It should be noted that the majority of interventions assessed for female sexual dysfuctions have been designed for heterosexual women in a relationship. There is a lack of representation of people from the LGBTQUIA+ community or people who are not in a committed relationship. Another important limitation of

these studies is the exclusion of people with mental illness, post-traumatic stress disorder and a history of violence/sexual assault. However, it was found that people suffering from mood disorders and victims of violence were over-represented among those suffering from genital and pelvic pain. Finally, because of the format of the platforms, people who are unable to read, write, understand the language of the program, or use technological tools independently are forgotten by the studies. This highlights the need to continue to study these DTx in order to propose solutions for improving or expanding the beneficiaries. A bias regarding DTx compliance should also be noted. The people included in each of the studies were volunteers and this has a strong impact on their motivation, realistically, adherence to the program was significantly affected. In real life situations, attendance, motivation and adherence to treatment may be lower. Regarding ethical considerations, data management are to be raised in order to guarantee the respect of good practices. Digital therapies include different types of online coaching that can integrate alternative therapies that are not validated and/or at risk of sectarian aberrations. Also, digital therapies require a strict framework concerning the actors involved in the elaboration of these programs and their roles with patients in order to avoid falling into the domain of the illegal practice of medicine. A requirement to have diagnosis established before starting the online program could be a strategy for recruiting beneficiaries. Also, the data shared by the patient during the program must be subject to medical confidentiality and the anonymity of the patients integrated in the program must be protected. Online programs should comply with good practice guidelines and treatment recommendations for the various pathologies. It must be made clear to the patient that these therapies are a complement to the current treatment of vulvar pain. They are not a substitute for medication, physical therapy or psychological therapy.

Recommendations

The first need highlighted in this scoping review is for more studies about digital therapies for vaginismus and vulvodynia. Further evaluation of these digital interventions is needed through follow-up studies of patients who have benefited from these programs. This work must be encouraged and continued in order to propose a better accompaniment of people suffering from genital-pelvic pain. Then, the need for multidisciplinary support was noted in every source included in this study. Regardless of the medium, it is therefore essential to implement a transdisciplinary strategy involving different actors to support patients in the relief of vulvar pain and vaginismus. Although online programs allow for better accessibility, more regular care and greater autonomy for patients, they are not necessarily exhaustive therapies and must be used in addition to therapies that take place in person. These internet interventions are not intended to replace medical care but to provide a link between consultations to ensure support at each stage of the care process. In fact, emerging

evidence of DTX's effectiveness emphasizes the indication that internet- based treatment could be incorporated into clinical practice as a complement to clinical treatment The idea would be to fill the gaps in care by adding the use of support in the practice of caregivers and allowing access to patients. The existence and usefulness of these interventions should then be integrated into the training of those involved in the care of people with chronic vulvar pain. They would be partly responsible for disseminating these online services to their patients in order to complete their follow-up.

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Type of study	RCT prospective : 6 month follow up + intention to treat analyse	RCT prospective : 6 month follow up + intention to treat analyse	Multi-centre RCT prospective : 9 month follow up + intention-to-treat and also per protocol approaches	RCT prospective	Randomized trial Prospective study during 12 week treatment
Aims	Compare participants using the internet-based guided self-help training Vaginismus-Free with those assigned to a waiting control group	investigate the efficacy of a newly developed Internet-based guided self-help intervention for GPPPD.	Provide a novel and better understanding regarding the treatment of vulvodynia and the role of internet-based treatment as a complement to standard care for women suffering from vulvodynia	Evaluate an Internet-based psychological treatment program for FSD	Compare the effect off self help digital interventionby comparing self help group to counseled group
Study sample	77 heterosexual women with vaginismus (6month at least with no penetration)	200 women with GPPD	99 heterosexual women with vulvodynia	39 heterosexual women with fuction sexual disorder FSD engaged in a stable relation ship + their partners	58 women survivor of breast / gynecological cancer
Type of digital interventions	CBT based multidisciplinary program + ACT component 6 week treatment 30 minutes / day 6 modules Support : videos, audiofiles, self assessment Online follow up by e coach mindfluness + pelvic exercice+ body exposure exercise with dilatators/fingers	CBT based multidisciplinary program + ACT component 6 week treatment 30 minutes /day 6 modules Support : videos, audiofiles, self assessment Online follow up by e coach mindfluness + pelvic exercice+ body exposure exercise with dilatators/fingers	ACT/ CBT based program 8 to 16 weeks program 1 to 2 session of 45-60 min/ week Education, relaxation, cognitive restructuring, body exposure fingers and dilators, preparation for sexual intercourse Support: text, videos Online follow-up by coach	**"Revive" program**: internet based CBT program for women and partners: 10 weeks program - 5 modules only psychological approach program supports : text files follow up by therapist online	CBT based program + multidiscplinary techniques 12 week programm Educational, psychological and physical coaching +/- 3 in person appointments with counselor for one arm (36 patients)
Inclusion criteria	- No penetration possible in the last 6 month - No higher than 1 point on the PEQ (questionnaire - In a heterosexual relationship for at least 3 months - Internet access - Sufficient wrtient/ reading skills in german - Willing to give informed consent	- No penetration possible in the last 6 month - No higher than 1 point on the PEQ (questionnaire - +18 years old - In a heterosexual relationship or heterosexual partner - Internet access - Sufficient writing/ reading skills in german - Willing to give informed consent	- Symptoms of vulvodynia for at least 6 months, and confirmation of the medical diagnosis at the gynaecologist's appointment after study recruitment from waiting lists for clinical treatment, or by the woman herself following study recruitment through social media. - Access to a computer with internet connection. - Age of ≥18 years. - A Swedish personal identification number for access to the treatment platform.	- Currently experiencing FSD - In a stable hetero- sexual relationship - Over 18 years of age - Have regular Internet access; - Willing to complete three outcome questionnaire measures at different time points - Willingness and motivation from partners to participate in treatment - Commitment to at least 3 hours a week, for a minimum of 10 weeks to complete the treatment program.	- Women from tumor registrary - survivros of breast cancer or gynecological cancer - 1 to 7 years post diagnosed of localized breast/ gynecological caner - No active treatment other than homing therapy - Committed in a sexual relationship for at least 6 months - Partners willing to participate to the program - close enough to attend in person counseling - Writing/reading skill in English - Internet access
Exclusion criteria	- Previous PTSD - current/ previous psychosis or disossociative symptoms - current substance abuse or dependency - Current depression or bipolar disorder - current treatment fr vaginismus	- Previous PTSD - current/ previous psychosis or dissociative symptoms - current substance abuse or dependency - Current depression or bipolar disorder - current treatment for GPPPD	- Unclear diagnosis at the screening interview. - Ongoing examination/treatment related to vulvodynia. - Lack of fluency in Swedish, since the treatment is delivered in Swedish. - Severe, acute, or untreated mental illness or substance abuse.	- current other psychological treatment - current other medical treatment for FSD	- Ongoing cancer treatment - FSFI > 26,5 not scored as dysfunctional
Main outcome	Sucessful sexual intercourse (with penis insertion)	Sucessful sexual intercourse (with penis insertion)	Provoked vulvar pain	Sexual function evaluated by FSFI score : sexual desire, sexual arousal, lubrication, sexual satisfaction, orgasm, genital pain	Sexual function and sexual satisfaction

Secondary outcomes	Non-intercourse penetration Fear of coitus Sexual functioning Dyadic coping	Non-intercourse penetration Sexual functioning Dyadic stress coping Fear of sexuality and negative penetration-related cognitions.	Depression/ Anxiety Sexual function Quality of life.		Menopausal sexual interest emotionnal distress Quality of life
Data collection / measurement instrument : Primary outcome :	The seven-item **PEQ** will be used as a primary outcome measure: PEQ online or phone assessment. Questionnaire likert scale 0 = not attempted; 1 =attempted, but unsuccessful; 2 =attempted and sometimes successful; 3 = attempted and always successful = SCORE	The seven-item **PEQ** will be used as a primary outcome measure: PEQ online or phone assesment. Questionnaire likert scale 0 = not attempted; 1 =attempted, but unsuccessful; 2 =attempted and sometimes successful; 3 = attempted and always successful = SCORE	Self-reported pain : 0 (”no pain”) and 10 (” worst possible pain”) during vaginal intercourse + tampon test.	- FSFI = self report - Sexual Function Scale (SFS) - The Personal Assessment of Intimacy in Relationships (PAIR) Scale : self report questionnaire t	FSFI : Self report
Data collection / measurement instrument: Secondary outcomes	- PEQ 6 last items : Non coital penetration mesured - Fear of sexuality scale : 5 items Likert scale (1 = never to 5 = always) - Female Sexual Function Index (FSFI): 0-5 - Dyadic Coping Inventory : 5 pont scale 0 -4 - Client Satisfaction Questionnaire : CSQ-8 validated eight-item instrument with high internal consistency	- PEQ 6 last items : Non coital penetration mesured - Fear of sexuality scale : 5 items Likert scale (1 = never to 5 = always) - Female Sexual Function Index (FSFI): 0-5 - Dyadic Coping Inventory : 5 pont scale 0 -4 - Vaginal Penetration Cognition Questionnaire (VPCQ) self-report instrument 7-point Likert scale - Client Satisfaction Questionnaire : CSQ-8 validated eight-item instrument with high internal consistency	- Chronic pain acceptance questionnaire (CPAQ) self assessment - The Female Sexual Function Index (FSFI) - Female Sexual Distress Scale-Revised (FSDS-R) - Beck Anxiety Inventory (BAI) = score - Satisfaction with Life Scale (SWLS) : 5 items scale	Depression, Anxiety, Stress Scale (DASS21)	- Menopausal Sexual Interest Questionnaire (MSIQ) - Brief Symptom Inventory-18 (BSI-18) assessed emotional distress with a Global Severity Index (GSI) - The Quality of Life in Adult Cancer Survivors (QLACS)
Results in main outcome	**Significant increase in intercourse penetration** from baseline to 6 months	**ANTICIPATED RESULTS :** - increase in the ability to have sexual intercourse - positive cognitions toward vaginal penetration - decrease expected in genito-pelvic pain, fear of pain and penetration, and negative cognitions associated with intercourse and sexuality	- Significant lower pain in intervention group but no significant decrease in term of discomfort/fear at tampon test. - No significant differences in term of pain impact on sexual function	- Significant improvements in sexual function from pretest to posttest in IG - Significant improvements from pretest to posttest in levels of sexual desire - significant difference between the treatment and control groups in the frequency with which their female sexual dysfunction was perceived to be a problem - Significantly improvements in the relationship factors with their partner - No significantly greater improvement from pretest to post- test on any of the individual factors	- Significant increase in sexual function and sexual satisfaction in menopausal women - No difference on the sexual function between patients who had access to the counseling appointment and patients with only the online program.
Results in secondary outcome	- Significant increase between-group effects concerning non-intercourse penetration (self-insertion of a finger or dilator or insertion by the partner) in favor of the IG - Higher scores for self-insertion in IG - Significant decrease in fear of coitus was observed in IG - No significant difference in female sexual function within group and between group		- No significant differences in terms of « sexual activities besides intercourse » and « willingness to perform the tampon test ». - Significant higher pain acceptance and activity anegement in the intervention group - Significant lower pain intensity during intercourse in the intervention group	Improvements in all areas of sexual functioning (sexual desire, arousal, lubrication, orgasm, satis- faction, and pain) were significantly greater among those women who completed the program compared with those who received no treatment.	Significant decrease of emotional distress and significant better ratings of overall quality of life at post treatment