

Development of a self-help digital intervention for functional cognitive disorder: a theory- and user-centred approach

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Abstract

Background: Functional cognitive disorder (FCD) is a common and disabling condition for which accessible and evidence-based treatments are urgently needed.

Objective: We describe the planning and development stages of a new self-help mobile app intervention for FCD.

Methods: The UK Medical Research Council's Complex Interventions framework was followed. Theory- and user-centered approaches were adopted to develop Memento – a 6-week programme rooted on cognitive behavioural techniques and complementary principles (mindfulness, education, cognitive rehabilitation).

Results: A scoping review is presented. Thematic analysis of patient interviews identified 6 themes and 13 subthemes, including user needs, management strategies, opportunity and motivation. The treatment model places attentional dysregulation as the core symptom generator, around which treatment content was developed. Provisional insights from a focus group suggested the intervention is acceptable and credible. Facilitators and barriers were uncovered and addressed. The programme includes 7 modules, videos, patient stories, FAQs, and signposting to existing resources. Interactive features include a weekly memory diary and symptom checklist, tailoring of contents to symptoms, and homework tasks.

Conclusions: We used a systematic approach to develop a novel digital health intervention for FCD. Collaborations with key stakeholders enabled intervention development and optimisation. Feasibility, acceptability, and efficacy testing of this intervention are underway. Clinical Trial: N/A

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Original Manuscript

Development of a self-help digital intervention for functional cognitive disorder: a theory- and user-centred approach

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Abstract

Background: Functional cognitive disorder (FCD) is a common and disabling condition for which accessible and evidence-based treatments are urgently needed. We describe the planning and development stages of a new self-help mobile app intervention for FCD.

Methods: The UK Medical Research Council's Complex Interventions framework was followed. Theory- and user-centered approaches were adopted to develop Memento – a 6-week programme rooted on cognitive behavioural techniques and complementary principles (mindfulness, education, cognitive rehabilitation).

Results: A scoping review is presented. Thematic analysis of patient interviews identified 6 themes and 13 subthemes, including user needs, management strategies, opportunity and motivation. The treatment model places attentional dysregulation as the core symptom generator, around which treatment content was developed. Provisional insights from a focus group suggested the intervention is acceptable and credible. Facilitators and barriers were uncovered and addressed. The programme includes 7 modules, videos, patient stories, FAQs, and signposting to existing resources. Interactive features include a weekly memory diary and symptom checklist, tailoring of contents to symptoms, and homework tasks.

Conclusions: We used a systematic approach to develop a novel digital health intervention for FCD. Collaborations with key stakeholders enabled intervention development and optimisation. Feasibility, acceptability, and efficacy testing of this intervention are underway.

Highlights

- Functional cognitive disorder is a common and disabling condition, but currently there is no standard accessible treatment.
- A UK Medical Research Council's Complex Interventions framework combining theory and public involvement activities was followed within a multidisciplinary research team including people with lived experience, healthcare professionals and designers.
- A potentially scalable, flexible, and accessible self-help intervention may provide diagnostic explanations and management strategies to patients who would otherwise be unsupported.
- Feasibility, acceptability, and efficacy testing of this intervention are underway.

Introduction

Functional cognitive disorder (FCD), a subtype of functional neurological disorder (FND)(1), manifests with cognitive symptoms such as forgetting an intended action while in the process of carrying it out, difficulty recalling automatic information like PIN numbers, interrupted thoughts, and word-finding difficulties, that may superficially resemble dementia(1, 2). A discrepancy between the level of impairment reported and day-to-day function (also known as *internal inconsistency*) is the main distinguishing feature(1). Patients with FCD frequently seek healthcare services, accounting for around a quarter of individuals attending specialized memory clinics under the age of 65(2). FCD is also overrepresented in primary care, and in populations with other functional neurological disorders(3), post-mild traumatic brain injuries(4), and other systemic conditions. Excessive attention towards the self and cognitive processes(2), health anxiety about cognition, memory perfectionism(5), obsessive thought structures, neuroticism(6), poor global metacognition(7, 8), and abnormal emotional processing(7, 9) have been hypothesised as potential mechanisms for the symptoms(10).

Although there is limited data regarding prognosis, symptoms may not resolve in up to 85% if left untreated(11, 12), causing significant disability and distress to both patients and families, and severely impacting social functioning and work productivity(11, 13, 14). While efforts are underway to positively identify FCD patients(1, 15, 16), currently there are no randomised controlled trials of interventions targeting the specific mechanisms involved in FCD. Preliminary evidence for functional memory symptoms suggests that psychotherapy targeting negative memory beliefs and stress regulation(17) is potentially beneficial, but findings were inconclusive and need replication(18). Imported therapies from other functional disorders, including cognitive-behavioural-therapy (CBT), have been tried in practice but have yet to be rigorously investigated(9, 19-22). Also, while potentially effective, face-to-face interventions are limited by restricted expertise, heterogeneous framing of symptoms(23), cost, and stigma(24). Hence, patients are liable to present multiple times, request further referrals and investigations, with the potential for iatrogenic harm and unnecessary healthcare and societal costs(11). Thus, innovative and accessible evidence-based treatment options are warranted.

The rise in smartphone users represents an opportunity to increase access to evidence-based care and overcome the treatment gap(25), using similar treatment processes of traditional treatments. Of the approximately 350,000 healthcare apps available for download, most of which promising cognitive benefits, only a few are evidence-based. Furthermore, significant variations exist in how they are utilised(26), posing potential hazardous risks. However, potential barriers to feasibility and acceptability of remote interventions may also be unique to some FCD users including their short attention span, higher chances of overstimulation, busy schedules, comorbidities, and low digital literacy. Moreover, poor real-world user engagement with healthcare apps in general suggests that novel digital interventions need to consider users' main needs, preferences and requirements(27). A self-help intervention for FCD is yet to be developed.

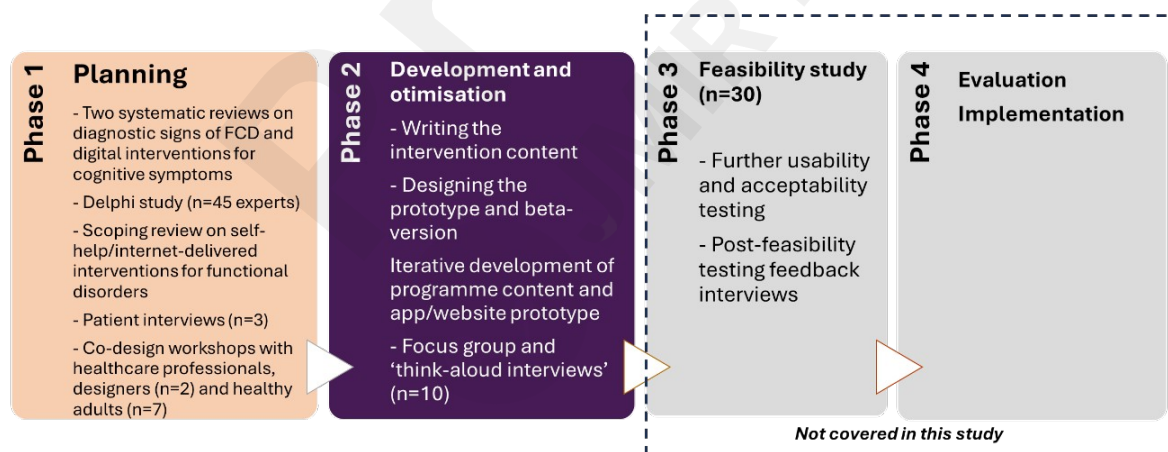
The aim of this paper is to provide a clear account of the planning and development stages of Memento, a novel self-help digital intervention for FCD, following theory- and user-centred approaches. We focused on a literature review and described how the feedback obtained from healthcare professionals and patients helped develop and tailor the content and platform design to

users' expectations, needs, and preferences. As the initial phase of a broader project, this paper is the first of ongoing studies including feasibility evaluation which will be a proof-of-concept prior to a future RCT.

Methods

Momentum was developed according to theory- and user-centred approaches(28). We followed the UK Medical Research Council (MRC) 2021 framework for Complex Interventions(29) in four interconnected phases: planning (phase 1), development and optimisation (phase 2), feasibility/piloting (phase 3), and evaluation and implementation (phase 4). This publication focuses on the first two phases of this development; for an overall work plan, see figure 1. Though these phases will be described separately, in practice, they took place as an iterative cycle. The theoretical basis drew on both primary research and existing theory, including a scoping review of CBT for functional disorders and remote interventions for conditions sharing mechanisms with FCD, and our own research which includes two systematic reviews and a Delphi study(16, 23, 30). The user-centred approach work was guided by selected interventions that incorporated co-design and usability testing studies(31-35), plus guidance documentation(28, 29, 36-40). Relevant literature on design thinking was also reviewed(41, 42).

Figure 1. Program development process according to Medical Research Council (MRC) 2021 framework for Complex Interventions(43).



Ethics approval was received from The North of Scotland Research Ethics Service (REC reference: 23/NS/0102). Description of the intervention development adheres to items on the TiDieR (template for intervention description and replication) checklist(40) and Guidance for Reporting Involvement of Patients and the Public (GRIPP)(44) (Supplemental file). The current study is part of the innovative training network ETUDE (Encompassing Training in fUncional Disorders across

Europe;<https://etude-itn.eu>)(45).

Phase 1: planning

Phase 1, step 1: reviewing relevant literature

We initially conducted two systematic reviews to better characterise the FCD population(16) and review the evidence on digital interventions for cognitive symptoms(30). This work yielded no specific treatments designed for FCD, bar a treatment protocol and a small trial of cognitive-behavioural-therapy versus compensatory strategies for functional memory symptoms post-concussion(46, 47). Next, a rapid scoping review of CBT in functional disorders and internet-delivered interventions for conditions sharing mechanisms with FCD was conducted, with the aim of gathering evidence on the most effective treatment approaches, programme theories, design and interactive features, and public involvement methods. Searches were conducted in PubMed, Embase, Web of Science and ClinicalTrials.gov in June 2024. We identified over 5000 results. Additional quantitative and qualitative literature was identified through reference-list searching and suggestions within our team, including published literature reviews. Therefore, we decided to focus on reviews and most relevant original research which was selected within our team (search strategy can be found in Supplemental file).

Phase 1, step 2: stakeholder's input

In our context, the most relevant stakeholders are patients with FCD and clinicians that will recommend this intervention. Patients were involved in the planning and development stages of this intervention in two steps: 1) in-depth qualitative semi-structured interviews (n=3) to gather in-depth user needs, experience with technology use including apps, current management strategies, to generate ideas about the content, format and delivery of the intervention; and 2) focus group including 'think-aloud interviews' (n=10) to obtain feedback on the prototype of a future self-help intervention. FCD patients from a neuropsychiatry service in Lothian, Scotland, UK were invited, with outreach extending to social media and an FND charity. Inclusion requirements for participants in the project were having a diagnosis of FCD, a smartphone and ability to use smartphone apps, and domain of English language. A £25 voucher was awarded for their contribution.

Delphi study

Prior to this work, we conducted an international Delphi study with 45 experts in cognition and functional disorders, from 12 countries(23). We gathered existing practices for management of FCD; 80% of the 45 clinician experts did not currently know any self-help or remote treatments for FCD patients. Those who answered "yes" recommended the neurosymptoms.org educational page, which

has not shown to improve outcomes in motor FND, despite patients' satisfaction. 91% of the clinicians said they were willing to prescribe a novel digital intervention for FCD. Clinicians mentioned they often felt unequipped to deal with this patient population and there was a concern over creating false expectations in a low-resource scenario(23). Methods, demographics, and FCD experience are described in a prior publication(23).

Interviews

The interview alignment was developed by the research team who is familiar with participatory design and assesses patients with FCD on a regular basis (Supplemental file). It includes questions about patients' symptoms and needs, technology use (experiences with apps and digital resources), and was further complemented by the COM-B model, a framework based on three interacting domains for behaviour change: Capability, Opportunity and Motivation(48). Interested participants received study details and interview invitations via email. Interviewees were given the right to discontinue their participation at any time or skip over questions that they do not wish to answer. Interviews were conducted via Zoom by VC, recorded (audio-only) with participants' verbal consent and transcribed. The transcriptions were filtered into relevant data extracts, which were then coded and analyzed using MaxQDA22(49). The first step involved familiarisation with the data (VC, LF) by repeated listening to audio recordings. This was followed by transcription and inductive and deductive thematic analysis to identify themes and subthemes that were discussed within the team (VC, LF, AC).

Co-design workshops

The team participated in two distinct co-design full day workshops with healthcare professionals from our network(50), healthy adults (doctorate students informing future users' perceptions) and UX/UI designers (n=7). They were relevant for decisions pertaining clinical priorities, the overall structure of the intervention, critical intervention features, and successful engagement strategies. Traditional stages of design thinking (empathy, define, ideate, prototype, test) were used to promote collaborative ideation(41). The first author (VC), with feedback from the participants, designed the initial wireframes of a FIGMA prototype to match the storyboard of the intervention, and the participants reflected on the user stories and proto-personas representing the future users (supplemental file).

Phase 2: developing and optimising the intervention

Treatment model and intervention content

Drawing on the research team's experience, evidence from the literature and the views and needs of target users, we started drafting the mechanisms of change of our FCD model and the intervention content. Our multidisciplinary research team included neurologists, a psychiatrist, and a health psychologist with experience in functional disorders and complex intervention development and internet-delivered programmes. Drafts of intervention materials were shared for comment and iteration for over a year.

Platform development

Both the contents of the intervention and the technical platform were developed *de novo*. The technical platform was developed primarily by VC and hosted in a no-code platform Cogniss® to be delivered via a mobile app. It is hosted on virtual servers in the UK and was reviewed to comply with GDPR and safety regulations.

Focus group including think-aloud interviews

In this step, ten participants with lived experience of FCD were presented the app prototype and asked to work through the prototype during 30 minutes and perform certain tasks: enter a module and explore it, listen to audio/video, explore attention training exercises, and complete a memory diary. Participants were encouraged to think aloud and make remarks and observations regarding their experience and usability aspects of the prototype.

At the end of these processes, a final userflow workshop took place including VC and two designers where a decision regarding the app userflow and main interactive features of the delivery platform was reached.

Table 1. Overview of stakeholder activities.

Overview of stakeholder activities (user-centred approach)		Outcomes
Delphi study (n=45)	Phase 1: planning	Gauging existing remote therapies for FCD across 12 countries Assess clinician's willingness to prescribe a self-help intervention
Workshop with healthcare professionals and patient representatives	Phase 1: planning	Discussion of priorities for digital health technologies and main barriers and facilitators (presentation of initial prototype and programme content)
Patient interviews (n=3)	Phase 1: planning	Gather user needs, preferences, motivations, and patterns of technology use

Co-design workshop with healthy adults and UI/UX designers (n=7)	Phase 1: planning	FIGMA wireframes Creation of storyboard, user-stories and proto-personas
Patient focus group (n=10)	Phase 2: optimisation	Usability and acceptability testing (think-aloud interviews) Discussion of main barriers and facilitators identified by the patients for optimisation of the intervention
Userflow workshop with UX/UI designers (n=2)	Phase 2: optimisation	Defining the main app features and userflow based on the feedback

Results

Phase 1: planning the intervention

Rapid scoping review of self-help CBT and internet-delivered treatments for Functional disorders

The findings from our scoping review are synthesized here according to their relevance for our intervention development. The largest body of evidence on internet-delivered interventions focuses on CBT-based interventions. These interventions target negative thinking and behaviours, making them a logical treatment candidate for functional disorders(51, 52). CBT-based self-help interventions for functional disorders have originally been developed in the form of workbooks and telemedicine(51-55). Much of the evidence for internet-based self-help approaches including internet-delivered CBT (iCBT) comes from psychiatric disorders like depression and anxiety, which are comorbid to around half of the patients with FCD(56). iCBT has been offered in chronic conditions sharing overlapping mechanisms with FCD including chronic pain, fatigue, insomnia, tinnitus, and other somatic conditions(57-61). It has also been tested in neurological patients, including for depression in epilepsy(62) and fatigue in multiple sclerosis(63), with small to large effect sizes, some involving patients with comorbid cognitive difficulties, which did not preclude treatment delivery(64, 65). Although results are mixed, iCBT may be as effective as face-to-face CBT in depressive disorders, and superior to waitlist control groups, offering greater accessibility and cost savings due to the limited therapist-time required(59-61, 66). Evidence also suggests that iCBT is generally acceptable and feasible, without significant side effects(67). More recently, mobile app-based CBT (mCBT) has been shown to be at least as effective as iCBT for chronic pain, ‘post-concussion syndrome’ and health anxiety(32, 35, 68). In both iCBT and mCBT, users are prompted to engage with different modules and access interactive tools, which minimises variability related to human contact (higher fidelity)(69) and allows transfer of therapeutic strategies to daily context(69). As an advantage, mCBT might be initiated shortly after symptom onset or exacerbation. Notably, preliminary evidence shows that mCBT might promote higher adherence rates than iCBT(70), which could be related to its unique features (e.g., push notifications)(71) and a so-called “digital placebo effect”(72). Interestingly, mindfulness-based interventions share characteristics with traditional forms of CBT and have shown benefit in various neuropsychiatric disorders, including in improving quality of life in seizure forms of FND(73-77). Brief trainings in focused attention and breathing forms of mindfulness may improve memory performance(75, 78), build self-compassion, and cognitive flexibility(79), with possible brain network change in areas involved in attentional and emotional processes(80, 81), which are likely relevant in FCD. However, we did not identify remote self-help mindfulness-based interventions in functional disorders. So far, evidence is scarce

regarding superiority of one treatment approach versus another (e.g., CBT vs mindfulness), and there is an empirical rationale for a combination of multiple approaches in disorders with multiple mechanisms like FCD.

In relation to guidance, remote interventions may be self-guided or include variable degrees of therapist support, including human or automated contact(59), and can be synchronous or asynchronous (platform- or user-initiated)(70, 82). A meta-analysis of 38 mental health controlled trials of written self-help CBT concluded that medium effect sizes were obtained, regardless of the type of support provided (guided self-help, self-guided and minimal contact (remote assistance but not therapeutic contact)(64), with the latter being potentially associated with larger effect sizes(64). For iCBT, results are mixed and it is not clear whether therapist or telephone forms of support provide additional benefit(67). Importantly, overall, both human and automated forms of support have proven effective, acceptable and associated with patient satisfaction(83). There is recent evidence suggesting that therapeutic alliance can also be achieved in unguided internet interventions(84). Overall, self-guided interventions may offer an initial strategy to enhance access to treatment, before sufficient resources can be secured for wider implementation(85).

As for design features, there is very little evidence regarding aspects associated with better engagement and effectiveness(71, 82, 86, 87). Studies often fail to explicitly describe design features precluding comparison and analysis of their effects in the outcomes, including users' satisfaction and behavioural change. Moreover, it is likely that design choices are influenced by the end-user population and the intervention approach. Regardless of choices made, evidence suggests that the main reason for lack of intervention adoption and low treatment adherence is failure to include users in the planning, design, and feasibility stages(38, 39, 88).

Phase 1, step 2: stakeholder's input

Interviews

Three patients (two males and one female, mean age: 61yo) participated in in-depth semi-structured interviews. Two patients were employed and the other retired due to FND-resulting disability. Interviews lasted 59-74min.

Thematic analysis identified 6 themes and 13 subthemes (Supplemental file). In relation to the main theme (**background information**), previous experiences including exposure to dementia were relevant for symptom development. Other factors identified were childhood trauma and previous head injury.

“My mother died with a diagnosis of frontotemporal dementia. I became concerned that some of my cognitive symptoms, perhaps, were that. And I did receive that diagnosis in about 2012. I did believe I was dying, and I am aware that I still have increased risk of dementia.”

The main **needs/pain points** were being able to resume social activities, being able to remember

people's names and reading. The need for **symptom validation** was also discussed.

"I was given the diagnosis of conversion disorder, and I was told I had a psychiatric disorder that it wasn't real. (...) I felt dismissed and left behind..."

The second theme (**treatment targets**) encompasses some of the main perpetuating factors including increased self-monitoring, anticipation of failures, hypervigilance and hyperarousal, avoidance, and excessive safety strategies and repetitive checking.

"I'm aware of trying to make sure everything is carefully done and logged. Still, I'm nervous about having forgotten to put something in"

"I'm concerned that I might forget things so super cautious to make sure that there's a very, very good record and track of everything that I've been doing and done."

Regarding **physical and psychological capability**, they endorsed psychological coping including trying to reframe their memory lapses as common, choosing not to engage in counterproductive thoughts, and using distraction, exercise, taking up new hobbies, and relaxation strategies. One patient mentioned that congratulating herself for her cognitive successes assisted in her recovery.

The patients looked up credible and useful sources of information outside the limits of a consultation room (**opportunity**), and there was a need for social support from family and perhaps to learn from others.

"it's a hard disorder to have and be diagnosed with. It's hard for them to really understand (...) even my closest friends and family."

The accessibility of a self-help intervention and the possibility of tracking symptoms were important motivators to try out a new intervention (**motivation**). Patients also endorsed the relationship between cognitive symptoms and sleep, stress or other physical symptoms like fatigue as a core aspect of their condition.

Finally, regarding **general use of technology**, all used teaching videos and/or mindfulness apps. Patients reported they would accept an app as part of their treatment, providing it was viewed as part of a wider treatment, and not used as a discharge strategy after diagnosis, in line with existing

data(58, 59).

Co-design and userflow workshops

Discussions held with healthcare professionals, healthy adults and designers focused on barriers and facilitators for the future intervention, and the treatment model. The main concerns of healthcare professionals and designers over a self-help intervention were low engagement, information saturation point, the need to adopt lay and consistent language and to tailor the programme to different illness backgrounds and comorbidities, namely anxiety and depression. It was also felt that the programme needed to be simple enough to allow for independent navigation given the self-help nature of the future intervention. This work inspired the prototype and the userflow of the future app that was presented to end-users in the patient focus group.

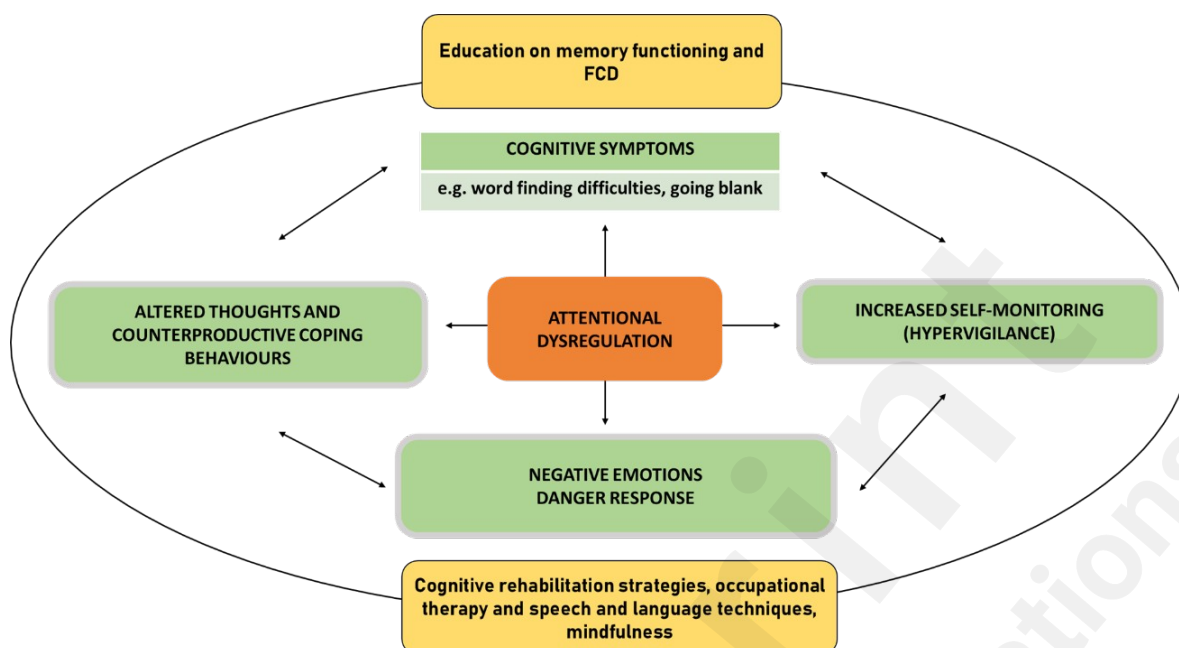
Phase 2: developing and optimising the intervention

Treatment model and intervention content

Our intervention content primarily uses 1) CBT with added elements of 2) education about memory and attention aiming at reducing the threat and increasing understanding of factors that predispose to symptoms, triggers and maintaining factors; 3) metacognitive strategies; 4) cognitive rehabilitation, 5) brief mindfulness practices to facilitate ‘bottom-up’ processing and more neutral interpretations of cognitive experiences by reducing hyperarousal, and 6) techniques borrowed from speech and language and occupational therapy for more specific symptoms (e.g. word-finding difficulties)(19, 89). The CBT-based model we propose considers four maintaining factors which are deemed to contribute to symptom chronification and distress in FCD: 1) self-monitoring motivating ‘top-down’ control, 2) anxiety about cognitive performance and negative emotions driving hyperarousal (fight-or-flight response secondarily to an increased awareness of cognitive symptoms), 3) bias in thinking including catastrophizing and generalisation, and 4) unhelpful coping behaviours including avoidance and safety strategies. This places the attentional dysregulation with attention directed to memory problems and deviated from the tasks at the centre of our treatment model (figure 2). The model invites patients to introduce behavioral modifications that reduce reliance on excessive safety strategies and is intended to promote tolerance to low stake cognitive failures and increased confidence in memory.

Figure 2. Treatment model highlighting the main maintaining factors for functional cognitive symptoms: 1) self-monitoring motivating ‘top-down’ control, intolerance to ‘normal forgetfulness’ and anticipation of failure (“I’m not going to be able to do this”), 2) anxiety about cognitive performance and hyperarousal triggering negative emotions, 3) bias in thinking including jumping to conclusions “They’ll think I’m stupid”, catastrophizing “I might have a dementia”

and black-or-white thinking “I can’t do anything right”), and 4) unhelpful coping behaviours due to a decreased confidence in cognitive abilities plus avoidance of situations or tasks that are perceived as cognitively challenging. With excessive attention being diverted to this loop, brain systems cannot perform normal tasks. The model emphasises potential CBT targets for therapy. FCD: functional cognitive disorder.



The development of the treatment content was guided by the structure of key interventions identified in our scoping review(90-93), and the mechanisms of change of our treatment model, considering the perspectives of end-users, and the challenges identified. Firstly, the programme provides an introduction to how normal memory and attention work, and an explanation of why FCD might develop considering individual vulnerabilities, triggers and maintaining factors, in light of a biopsychosocial model. Secondly, the patients are invited to challenge unhelpful thinking patterns, and initiate behavioural modifications based on an invitation to try out an alternative working hypothesis, founded on examples of short- and long-term costs of avoidance and checking. Thirdly, the intervention provides users with simple compensatory cognitive strategies to manage external and internal distractions in order to increase confidence, while overreliance on external aids and repetitive checking is discouraged. The last module focuses on recognising a correlation between symptoms of stress, anxiety and cognitive worsening. Optional content on the relationship between pain, fatigue and poor sleep with cognition, and some strategies on how to manage these, is provided to match users’ needs. Homework tasks are suggested at the end of each module to encourage patients to translate this knowledge into practice and promote self-management (table 2).

Table 1. Summary of the intervention targets, strategies and homework tasks. Post-module tasks relate to the aims of specific modules and are intended to catalyse positive changes and implementation of habits and techniques beyond the time of using the app.

Intervention target	Main intervention strategies	Tasks
Education (Modules 1 and 2)	- Education on cognitive symptoms, highlighting attention as a limited resource, essential for encoding and retrieval of memories; - Education on causes of cognitive difficulties and concept of "cognitive continua" from Wells(94); - Attention as a filter of other stimuli (e.g. show that we can't assess resources under pressure). - Functional cognitive symptoms as a function of predisposing, precipitating, and potentially reversible perpetuating factors, within a bio-psycho-social framework.	- Noticing other's memory failures. - Collect others' opinions about one's memory failures.
Increased self-monitoring and performance anxiety (Modules 2 and 3)	- Introduction to the CBT-based model with a focus on self-monitoring. - Introduction to the importance of refocusing attention on tasks in hand instead of focusing on symptoms and thoughts. - Address performance anxiety and fear of failure.	Recognise cognitive successes
Negative thoughts and illness perceptions (Module 3)	- Explore the relationship between thoughts and symptoms. - Offer alternative more helpful ways of listening to an "ally" voice that supports positive thinking. - Alternatively, techniques to create a distance to one's thoughts.	Look for potential triggers of cognitive symptoms and altered thoughts
Counterproductive illness behaviours including avoidance or withdrawal from activities; perfectionist standards (Module 4)	- Education on short- and long-term consequences of engaging in defensive behaviours such as avoidance and safety strategies - Inspire participants to overcome the fear of failing by "trying their brain out": getting away from avoidant loops, including cogniphobia.	Stimulate progressive challenge (starting by doing things less perfectly)
Techniques focused on increasing self-confidence and rehabilitative strategies (Module 5)	- Cognitive self-management and preventive strategies (e.g. intentional encoding, repetition, taking breaks, management of distractions, FOUR technique to facilitate encoding) - Introduction of habits and routines, and pros and cons of calendar use - Occupational therapy and speech and language techniques for specific symptoms e.g. word-finding difficulties.	Practicing and learned techniques
Techniques addressing stress and symptom management (Module 6)	- Education on stress and its cognitive effects (including individual variability, "low stress threshold", and self-perpetuating cycle of stress). - Helping the person understand physical symptoms and cognitive symptoms due to anxiety and stress (concept of brain-mind-body disconnection). - Cover emotional reactions to the symptoms (neurocognitive-specific health anxiety/hyperarousal, anger, frustration, blame, self-criticism) to increase emotion recognition	- Offering opportunities to integrate valued activities into daily life to achieve balance and counteract "boom and bust" patterns; - Identification of own's values: re-direct energy to activities that bring higher satisfaction.
Sleep and healthy mind-body relationship (Optional module)	- Sleep hygiene education, stimulus control and techniques on sleep restriction - General advice on exercise, healthy diet and medication management - Different symptoms related to each other (e.g., poor sleep exacerbating both fatigue and concentration difficulties)	
Self-focused attention and cognitive and physical hyperarousal	- Mindfulness exercises including: - Deep-breathing - Mindful meditation and walking; - Attention training exercises - Progressive muscle relaxation - Grounding and centering	Practice of exercises on demand.

Treatment platform

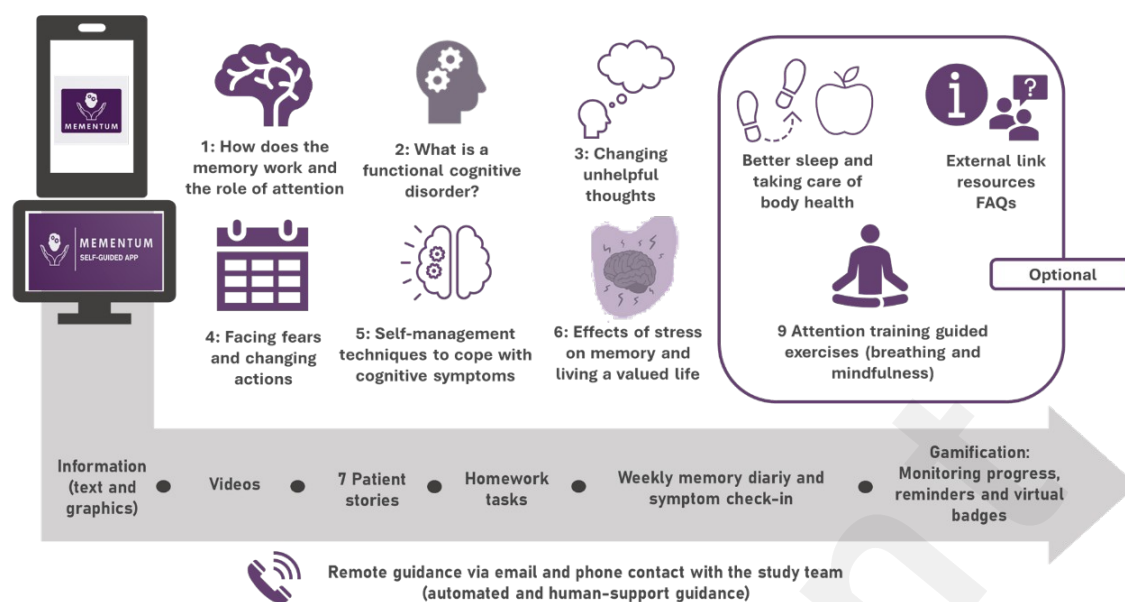
We used Morrison's conceptual framework(82) to plan for the initial four core interactive design features: social context and support; contacts with intervention; tailoring; and self-management. Considering the findings of our scoping review, we also included gamification and accessibility as essential points of this intervention. The initial design features were adjusted to accommodate the

feedback from the think-aloud interviews and the barriers and facilitators that were identified.

Access to the app is given via a study voucher and through a username and password created by the users. The content is conveyed via seven self-paced modules over a 6 week-period (figure 3). All modules follow the same structure: an introduction with objectives, text, graphics and videos, a homework task, and a summary of key messages. Modules have around 10 subpages and take about 30 minutes to complete. Forward and backward navigation are offered at the end of each sub-page. Module completion is marked and users receive a summary of the main messages, a badge and an email with further suggestions. Patients are encouraged to self-assess how helpful the module was for them. For each module, the user is invited to complete tasks related to the content. The app contains on demand video guided exercises based on mindfulness training, attention-training and grounding and centering, lasting up to 15 minutes. Six text and audio files of patient stories sharing recovery experiences were included. All learning videos and patient audio files last around 2 minutes. Users are asked to complete a weekly memory (5-point Likert scale) and symptom check-in to facilitate self-reflection, track progress, and tailor relevant content to symptoms. Data input into this diary can be reviewed visually through the 'My results' in users' profile. Patients are advised to dedicate around 2 hours per week to the programme, which they might divide and adjust to their routines and tolerance levels. Different tailoring elements were included within the reach of a self-help digital intervention, including a symptom check-in that retrieves a tailored pathway according to most troublesome symptoms reported by the patient.

The current platform delivers automated emails to motivate patients to engage with the program, and to remind them of the available features and suggested tasks. During the 6 weeks, users also receive technical guidance via 15-minute telephone calls with a neurologist every 2 weeks. The users are able to contact the research team via email and telephone on demand for technical support. Extra resources are provided via signposting, and FAQs are available for the users to view on demand.

Figure 3. Memento website and mobile app content.



Focus group and 'think-aloud interviews'

Ten participants with lived experience with balanced genders (five male and five female) participated in the focus group. The programme and app were deemed acceptable and rated highly for treatment expectancy and credibility. When asked "How much improvement in your cognitive symptoms do you think could occur with this programme?" we obtained a median of 5 out of 10 (range 1-8). For the question "how much do you really feel that this programme could help you reduce your cognitive symptoms?" participants rated a median of 6 (range 1-8). Participants welcomed the content being unlocked and having the possibility of browsing freely, as well as the ability to track their progress, so we added the possibility of seeing what content has already been completed and the answers provided in the memory diary.

They mentioned that motivation to engage with it is likely to wane if the app doesn't answer their questions nor is it compatible with their schedules. Based on this finding, some further adjustments were made, including the inclusion of a coached onboarding process when the users first use the app which introduces them the programme and its functions, reinforces the need for commitment for a successful outcome, and shows the expectations for the programme in a clear manner. A day counter and suggestions for the next task in the programme were added to the dashboard to facilitate engagement since day one, and users can save favourite content. One participant suggested that too much focus on a memory diary could increase self-focus on the symptoms, so this was set as an optional content and we suggest it to be completed no more than once a week. Specific strategies, patient recovery stories and practical examples were requested and included as a form of additional support (supplemental file). Special attention to user-friendliness and intuitiveness but also to accessible

language, made us avoid long blocks of text and technical jargon, and a preference was given to different formats including audio, video and visuals. An overview of the interactive features is provided in table 3.

Table 3. Intervention core design features.

Social context and support	1. Guidance on treatment progress and technical support offered every 2 weeks via 15-minute telephone calls with a clinician. 2. Patient stories (information about real users).
Contacts with the intervention	1. Asynchronous contact via email (both automated sending links for the programme and motivational messages, and user-initiated) (no limit). 2. Contact promoting app usage and engagement (push and in-app notifications).
Tailoring	1. All modules remain open (order is recommended but not mandatory). 2. Suggestion of a personalized pathway tailored to users' symptoms (symptom checklist). 3. Search bar: topical selection based on users' search 4. Favourites: option to save content with increased relevance to the users
Self-management	1. Weekly memory diary: 'How would you rate your memory over the last week?' Answered on a 5-point Likert-type scale ranging from very poor to excellent (symptom log) 2. Homework tasks; 3. Independent work through modules and attention-training and mindfulness video exercises. 4. Access to FAQs and external link resources via a support website.
Accessibility	1. Tour of the treatment package and app features (onboarding) 2. Easy to use and intuitive (e.g. "Up next" feature) 3. Different content formats (text, graphics, video, audio) 4. Lay language, technical jargon avoided, conversational tone in these modules, speaking to the user in the second person 5. Bitesize chunks with compressible text, allowing patients to skip less relevant content 6. Forward and backward navigation are offered at the start and end of each sub-page
Gamification	1. 'Up next': dashboard feature where users can see a list of tasks to complete next in the programme according to a pre-defined setting. 2. Progress bar during activities. 3. Virtual 'badges' as a reward for module and programme completion. 4. Day counter: dashboard feature allowing users to track their days in the programme. 5. 'My results': area in the users' profile that provides a summary of the progress in the programme and memory diary/symptom check-in entries.

Further barriers and facilitators were advanced by patients and grouped together in table 4. These were taken into consideration in the final design stages before testing.

Table 4. Main facilitators and barriers identified by users to engage with the app.

Intervention characteristic	Facilitators	Barriers
Engagement	▪ Credible sources ▪ App being able to record progress and validation of efforts made to improve ▪ Possibility of saving favourite content ▪ Wanting to be informed about their condition and motivation to recover ▪ Content that is relevant ▪ Tailored to patients needs and questions ▪ Flexibility of digital complementing in-person treatment ▪ Free ▪ Portable (independent of time and place)	▪ Learning saturation point ▪ Screen time and overstimulation ▪ Lack of human interaction: wanting to live a life 'off-screens' ▪ Low user retention (not enough prompts to use the app) ▪ Forgetfulness and concentration problems ▪ Minimum of digital literacy ▪ Competing with work and other life commitments
Symptom monitoring (e.g. memory diary, symptom check-in)	▪ Ability to review progress ▪ Follow the course of the programme ▪ Gamification elements	▪ Drawing attention to the symptoms can exacerbate self-monitoring and hypervigilance ▪ Repetitive task ▪ Inability to see improvement at short-term
Information	▪ Techniques to apply in daily life with practical examples ▪ Relationship between cognitive symptoms and other symptoms like fatigue ▪ Knowing what to expect, variety of symptoms ▪ Accessible with various formats: video, text, audio ▪ Acknowledge there is nothing the patients have done wrong/not their fault	▪ Not knowing what information is being the most helpful ▪ Emphasising the frequency of memory lapses in the general population might be counterproductive, as it may be interpreted as patronizing and dismissive ▪ "Non-adjustable" information
Patient stories	▪ Learning from others' experiences ▪ Validation of symptoms	▪ Stories gathered not resonating with the patients or their situation
Video guided-exercises	▪ Having everything in one place ▪ Having clear instructions on how to do the exercises ▪ Secondary benefits for stress management	▪ Not enough prompts to engage with these resources ▪ Poor concentration ▪ Difficulty following instructions

Discussion

This publication presents the planning and development stages of a new self-help digital intervention for FCD, delivered via a mobile app. The treatment of FCD remains largely unexplored, and specialised services are often inaccessible. As so, there is a major need for more accessible evidence-based treatments for FCD that can bridge the treatment-demand gap and offer early post-diagnostic support. This intervention (Momentum) was built around a treatment model that aims to address and counteract increased self-monitoring and hypervigilance to cognitive symptoms, as well as modify unhelpful thoughts and behaviours that diverge attention to the symptoms, with the end-goal of 'freeing up' attention for cognitive tasks. This study followed a standard complex intervention development framework(43), addressing numerous calls for a transparent intervention development process in order to minimise research waste and improve replication in research(28, 29, 40). To the best of our knowledge, this is the first intervention that was co-designed with FCD patients and followed such a systematic approach before intervention testing.

As part of this study, we expanded on the current knowledge about first-person descriptions of unmet needs of FCD patients(95), who often experience stigma and reduced quality of life. These findings exposed aspects related to physical and psychological capability, opportunity, motivation and patterns of general technology use by FCD patients, all of which may inform the development of future much needed interventions for FCD. For example, by providing the participants with clear instructions for how to access modules and complete tasks, both psychological capability and motivation are targeted. The self-guided nature allows patients to adjust the treatment around their schedules in a flexible manner (opportunity). Engagement is further reinforced with the use of automated emails and push notifications that prompt the participants to log in. Further, the findings from our focus group provided provisional insights that this digital intervention is convenient, credible and acceptable as an alternative to face-to-face psychotherapy. This combination of theory- and user-centred approaches aimed to ensure that both treatment content and delivery platform are relevant and potentially effective, potentially increasing the chances of future adoption and user engagement. This also reduces tokenistic approaches in healthcare, allowing patients to engage in the self-management of their condition and giving voice to an underserved group in research - those with cognitive complaints. The cross-disciplinary nature of the study and the inclusion of people with lived experience in the research team also provided opportunities for discussions around barriers and facilitators specific to FCD. We plan to continue doing so during the feasibility and implementation steps, with qualitative interviews post-intervention testing.

As healthcare professionals often report the lack of appropriate resources to offer to FCD patients, their willingness to follow FCD patients might be reduced, promoting a sense of dismissal(23). Together with the long waiting lists and limited time per consultation, there are obvious barriers to the adequate management of FCD. This increases patients' perception of a lack of social support and symptom validation, aggravating prognosis and leaving patients to seek alternatives for symptom relief, some of which may carry iatrogenic risks. A potentially scalable and accessible self-help intervention may provide diagnostic explanations and management strategies to patients who would be otherwise unsupported, particularly as they suffer from a condition that is often 'invisible' and perceived as more benign. The availability of a treatment option may also help legitimise their condition near their friends, family and employers. The ability to self-monitor their condition and a sense of hope and social support via a digital tool may also further promote the placebo effect,

inherent to any intervention, and already demonstrated in FCD(72, 96).

Limitations

Some limitations need to be considered. Patient no-shows amongst those who had initially agreed to interviews, and the absence of a dedicated FCD charity conditioned low patient recruitment for interviews and focus groups. This mirrors difficulties encountered in similar studies(31). Hence, the views included might have biased the content and design of this intervention, however, the interview questions focused on main needs, symptoms and perceptions of technology in a broad sense rather than focusing on specific intervention content or features, and the thematic analysis followed a standard model in the field of behavioural interventions (COM-B model). The efficacy of traditional individual CBT might not translate well into a self-help format, and this intervention will need to be subsequently tested for feasibility and efficacy to determine whether it can be successfully integrated into care. Future implementation of this intervention may face some hurdles such maintenance costs and complex regulatory approvals. While the delivery of a standardised treatment via an app may increase treatment fidelity and accessibility, it is dependent on users' digital literacy, motivation, and interleaves with users' routines. The fact that patients with FCD can present with diverse comorbidities and illness backgrounds may limit the success of this intervention. Future trials may help inform which participants are most likely to benefit from this intervention. Also, FCD as a concept is relatively new, and research is still evolving. An example is research around impaired metacognition, which in theory would be a treatment target, but metacognitive therapies have failed to provide benefit to this population(8, 10).

Conclusion

Momentum is a novel digital intervention for patients with FCD. According to the MRC complex intervention development framework, future feasibility, acceptability, and usability testing testing will provide pilot data to a full-scale RCT and further patient feedback. Future economic analysis will assess the impact of this and similar interventions currently under development(46) on FCD service delivery efficiency. The intervention is designed to be made available at no cost within for patients with an FCD diagnosis formally established by a clinician, as part of a 'stepped care' approach for patients with FND(97). While we expect potential improvements to be needed, to our knowledge this is the first potentially scalable, evidence-based and personalised treatment for people affected by FCD.

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Declaration of interest: JS reports personal fees from UptoDate, outside the submitted work, runs a self-help website for patients with functional neurological symptoms ([www. neurosymptoms.org](http://www.neurosymptoms.org)) which is free and has no advertising, provides independent medical testimony in personal injury and negligence cases regarding patients with functional disorders, and is secretary of the International Functional Neurological Disorder Society. He is a Chief Scientists Office NHS Research Scotland Career Researcher. AJC is a director of a limited personal services company that provides

independent medical testimony in court cases on a range of neuropsychiatric topics on a 50% pursuer 50% defender basis, a paid associate editor of the Journal of Neurology Neurosurgery and Psychiatry, and unpaid president elect of the International Functional Neurological Disorder Society.

CRedit Roles: VC – writing – first draft, editing and revision; conceptualization; data acquisition; formal analysis; LF – writing – editing; supervision, funding acquisition; JS - writing – editing; supervision, funding acquisition; AC - writing – editing; supervision, funding acquisition.

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Supplementary Files

Multimedia Appendixes

Supplementary files.

URL: <http://asset.jmir.pub/assets/7947f5815232cfedbc74dd417b61b690.docx>