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Pilot feasibility randomised controlled trial of cognitive–behavioural therapy for functional cognitive disorder after concussion

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ABSTRACT

Background Functional cognitive disorder (FCD) may be common after a concussion, and no evidence-based treatment options are available. The current study evaluated the feasibility of a novel cognitive–behavioural therapy (CBT) protocol tailored to FCD after concussion.

Methods Participants were randomised to CBT (n=11) or the current standard of care, cognitive rehabilitation (n=13). Both interventions consisted of eleven 50 min manualised videoconference sessions. CBT involved cognitive reappraisal and exposure-based strategies. Cognitive rehabilitation involved traditional memory compensation strategy training. Prespecified feasibility criteria were set for recruitment, perceived credibility, patient adherence, therapist protocol compliance and retention. The primary efficacy outcome was the Multifactorial Memory Questionnaire-Satisfaction (MMQ-S). The first five CBT completers completed a semistructured interview about their experience with the intervention.

Results Most feasibility benchmarks were met, as 86% of invited patients consented, 96% of participants rated their intervention as credible, participants attended 96% of sessions, therapists covered all essential content in 94% of sessions and 100% of participants completed the post-treatment evaluation. Both groups improved on the MMQ-S. Post-treatment MMQ-S scores were similar between groups (Cohen's d=−0.05 (95% CI [−0.86, 0.75])). Two themes resulted from the qualitative data analysis, which highlighted aspects of the CBT interventions that participants valued.

Implications This pilot trial supports the feasibility of CBT tailored to FCD after concussion and suggests that patients with FCD may benefit from either CBT or standard cognitive rehabilitation. A larger trial is needed to evaluate the efficacy of these interventions for FCD after concussion and potentially FCD in other clinical contexts.

Trial registration number NCT05581810.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Functional cognitive disorder (FCD) is characterised by distressing and/or disabling cognitive symptoms that are not attributable to structural brain injury or disease. Concussion may be a common precipitant of FCD. There is no known effective treatment for FCD after concussion. In related health conditions, cognitive–behavioural therapy (CBT) has been shown to reduce symptoms and improve functioning.

WHAT THIS STUDY ADDS

⇒ We developed and evaluated a novel CBT protocol tailored to FCD after concussion. In a feasibility randomised controlled trial, we compared CBT to cognitive rehabilitation, the current standard of care for persistent memory symptoms after concussion. Our results suggest that CBT is acceptable to and well tolerated by individuals with FCD after concussion. Both groups improved on primary and secondary outcome measures, suggesting that FCD is a treatable condition. Qualitative exit interviews with CBT completers suggest they valued its format, applied CBT skills in daily life and formed more positive views of their memory ability.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This study is an important step towards better treatment for adults with persistent memory symptoms after concussion and for FCD following other precipitants. The study findings will inform the design of a larger, phase III randomised controlled trial focused on testing efficacy.

INTRODUCTION

Up to 50% of people who sustain a concussion continue to experience memory and other cognitive symptoms 1 year after their injury.[1 2] These symptoms are minimally correlated with performance on neuropsychological tests[3–5] and neuroimaging metrics of structural brain injury.[6–8] Some individuals with persistent cognitive symptoms may have functional cognitive disorder (FCD).[9 10] FCD is a subtype of functional neurological disorder (FND) characterised by prominent cognitive difficulties that are not fully attributable to brain injury

or disease.[11] FCD can be precipitated by a variety of events or situations that raise a person's concern about their brain health and cognition, but trauma to the head may be a particularly common trigger.[12]

The mechanisms underlying the development and maintenance of FCD are not well established but are thought to overlap with other FND subtypes.[12] One likely perpetuating factor is avoidance behaviour.[12–14] Individuals who find memory lapses distressing are motivated to avoid them. People with memory concerns after concussion may specifically avoid activities with cognitive demands and engage in relatively subtle avoidance ('safety') behaviours such as repeated checking (eg, that they turned off the stove or locked the door)[10] or increased reliance on cognitive compensatory strategies.[15] Another likely perpetuating factor for FCD is catastrophising,[14] the tendency to perceive symptoms as concerning, problematic, intolerable or otherwise threatening. Catastrophising after a concussion is associated with cognitive symptoms that are disproportionate to any objective cognitive impairment.[16] Avoidance behaviour and catastrophising should be modifiable with cognitive–behavioural therapy (CBT) based on previous research in related health conditions, such as chronic pain[17] and persistent postural perceptual dizziness.[18]

The current pilot study evaluates a novel CBT protocol for FCD after concussion. We had three aims. The first aim was to establish the feasibility of the trial methods, including the CBT protocol. Feasibility was assessed according to prespecified criteria for recruitment, treatment credibility, patient adherence, therapist compliance and retention. The second aim was to provide a preliminary estimate of treatment efficacy. We chose cognitive rehabilitation as the comparator because it is recommended in clinical practice guidelines for concussion,[19] despite the limited evidence for its efficacy. We view CBT as a better theoretical fit for FCD because it directly targets undue memory concern, whereas cognitive rehabilitation involves teaching patients to compensate for the kinds of memory impairments typical of severe traumatic brain injury but not concussion. We hypothesised that CBT would be more effective than cognitive rehabilitation for FCD after concussion, but the present pilot-phase study was designed to explore a comparative efficacy signal and was not powered to confirm superiority. Our third aim was to learn about participants' experience with CBT and elicit constructive feedback for improving its delivery.

METHODS

Study design

The current study was a pilot feasibility randomised controlled trial with qualitative exit interviews. Reporting follows extensions of the Consolidated Standards of Reporting Trials. The study protocol was registered on ClinicalTrials.gov (#NCT05581810).

General procedures

We recruited participants with concussions into an in-progress FCD characterisation study from two sources: referrals from two concussion clinics in the Greater Vancouver Area and a list of participants who had recently completed a concussion research study[20] and agreed to be contacted about future research opportunities. As part of the characterisation study, participants underwent neuropsychological testing, brain MRI and a neuropsychiatric evaluation. At case conference meetings, neuropsychiatrists and neuropsychologists determined by consensus if each participant met diagnostic criteria for FCD after concussion: (1) one or more cognitive symptoms, (2) evidence of internal inconsistency, (3) symptoms are not better explained by another medical disorder and (4) symptoms cause clinically significant distress or impairment, or warrant medical evaluation.[11] Participants who met the criteria were recruited into the present study.

In addition to having a consensus diagnosis of FCD, participants had to (1) be between 18 and 65 years of age, (2) be fluent in English, (3) have sustained a concussion according to the WHO Neurotrauma Task Force definition[21] between 6 and 24 months ago, (4) demonstrate adequate test-taking effort on performance validity testing, operationalised as passing both the 21-Item Test and Test of Memory Malingering and (5) have regular access to an internet-connected device. Exclusion criteria were (1) unstable/serious medical condition, (2) unstable/severe mental illness, (3) active/suspected drug use disorder, (4) taking a medication with a known side effect of memory impairment and (5) contraindication for MRI. Participants had unrestricted access to usual care during the study. Eligibility was assessed over the phone by a research assistant.

Randomisation, allocation concealment and blinding

Participants were randomised (1:1) to CBT or cognitive rehabilitation, stratified by the Multifactorial Memory Questionnaire–Satisfaction subscale (MMQ-S; cut-off=27, the mean score in a prior FCD study[22]). A database manager generated and managed the randomisation list, concealing it from the research team. Participants were aware of their group assignment but were blinded to the study hypotheses. It was not possible to blind study therapists. Outcome measures were all self-reported, so assessor blinding was not applicable.

Interventions

Both interventions were manualised and involved eleven 50 min one-on-one sessions over Zoom videoconference, with collaboratively set homework assignments between sessions. The same therapists (graduate students in clinical psychology) delivered both interventions. Sessions were audio recorded. The intervention manuals specified limited tailoring opportunities, including that up to two additional sessions to cover all required content was permissible. Therapists studied the treatment manuals and practised with mock participants before joining the

study, and then participated in weekly group supervision led by a neuropsychologist (NDS) during the study.

Cognitive-behavioural therapy

The CBT protocol was designed to help participants normalise how they use their memory and to reduce reactivity to memory lapses. Avoidance of activities and situations (in which patients attributed risk of memory failure) was targeted with in vivo exposure, while safety behaviours (eg, excessive memory compensatory strategy use and checking) were gradually phased out with behavioural experiments. Participants learned how to identify common 'thinking traps' and use cognitive reappraisal to reinterpret memory lapses. The CBT protocol included additional minor components: developing a plan to better manage factors impeding attention (eg, poor sleep, pain and stress); relaxation training; monitoring memory 'successes' and allowing for automaticity (vs increased effort) when remembering and retrieving information. The content of the sessions was adapted from CBT-based interventions for functional neurological symptoms.[23 24] See online supplemental table S1 for an outline of the content of sessions.

Cognitive rehabilitation

This intervention included education about memory mechanics and training and practice with internal (eg, implementation intentions) and external (eg, smartphone reminders) memory compensatory strategies. The content was adapted from published cognitive rehabilitation manuals, primarily Shum *et al*.[25] This control intervention was designed to match CBT on attention (ie, session format, duration and frequency) and perceived credibility. See online supplemental table S2 for an outline of the content of sessions.

Quantitative measures

Feasibility measures

We prespecified feasibility targets (criteria for advancing to a definitive trial). Feasibility targets are listed in the second column of table 1. Credibility was assessed with the Credibility/Expectancy Questionnaire,[26] administered between the first and second treatment sessions after the therapist explained the rationale and content of the treatment. We replaced 'trauma symptoms' with 'memory difficulties' throughout. The credibility scale is calculated by averaging the first three items (eg, 'At this point, how logical does the therapy offered to you seem?').

Therapist compliance with treatment manuals was independently rated by two graduate students in clinical psychology. Neither were treatment providers in this study. Following a calibration exercise, the raters audited 20% of the sessions (randomly selected) and used a standardised fidelity checklist to indicate which essential therapist actions they observed. Missing or inadequate (ie, poor quality) recordings were replaced with another randomly selected recording. Raters completed a secondary measure of therapist compliance for both interventions, the Cognitive Therapy Rating Scale (CTRS).[27] The 11 items of the CTRS map onto two subscales measuring general therapeutic skills and CBT-specific skills. Higher CTRS scores indicate greater therapist fidelity to CBT within treatment sessions.

Primary efficacy outcome

Memory concern

The primary efficacy outcome was the MMQ-Satisfaction,[28] which measures general memory concern (eg, 'I am generally pleased with my memory ability' reverse scored) The MMQ-S has good internal consistency (α=0.95), test–retest reliability (r=0.93), and content, convergent, discriminant, and concurrent validity,[28] as well as responsiveness to change.[29] Lower scores represent greater memory concern (lower satisfaction). Scores ≥30 (T-score ≥40) indicate normal-range memory concerns according to normative reference values from the MMQ-S manual.[30]

Secondary efficacy outcomes

Patient Global Impression of Change

Patient Global Impression of Chang (PGIC) was measured using the following single-item scale: 'Since beginning

Table 1 Feasibility benchmarks for a successful pilot trial

Feasibility outcome	Acceptable range	Observed value		
		CBT group (n=11)	Cognitive rehabilitation (n=13)	Both groups (N=24)
Recruitment	>50% of eligible participants agree to enrol	N/A	N/A	86%
Treatment credibility	>50% of enrolled participants rate the intervention as above midpoint (ie, 4.5/9) on the credibility factor of the CEQ	100%	92%	96%
Patient adherence	>70% of participants attend at least 8 sessions	100%	92%	96%
Therapists compliance	Therapists cover 95% of essential element content	96%	92%	94%
Retention	>80% of randomised participants complete the primary outcome measure immediately post-treatment	100%	100%	100%

CBT, cognitive–behavioural therapy; CEQ, Credibility/Expectancy Questionnaire; NA, not available.

treatment, how would you describe the change (if any) in your level of satisfaction with your memory ability? Select one answer.' Participants provided ratings on a 5-point scale going from much worse to much better. A PGIC tailored to the outcome of interest has been used in prior trials to assess clinically meaningful improvement.[31]

Bothersomeness

Bothersomeness of memory symptoms was assessed using a one-item scale adapted from the COgnitive Behavioural Therapy for Dissociative non-Epileptic Seizures trial[32]: 'How bothersome were your cognitive symptoms overall in the past 4 weeks?' rated on a 7-point scale going from not bothered at all to very bothersome.

Mechanistic outcomes

Avoidance

Avoidance behaviour was assessed using multiple self-report measures. On the Fear-Avoidance of Memory Loss scale,[33] participants rate their agreement with 23 statements, 9 of which make up the Avoidance subscale (eg, 'I can't be as social anymore because I forget things too easily'). We also administered the Memory Compensation Questionnaire (MCQ).[34] The External and Relative subscales of the MCQ, respectively, measure the extent to which participants use external memory aids and rely on others to remember.

Catastrophising

The Symptom Catastrophising Scale was created for concussion studies[35] from the Pain Catastrophising Scale[36] by replacing 'pain' with 'symptoms' throughout. Higher scores reflect greater rumination, magnification and helplessness.

Qualitative data

The first five participants to complete CBT were invited to a semistructured interview over Zoom videoconference. Interviews were conducted by a trained undergraduate student and lasted approximately 25 min. A semistructured interview guide (online supplemental material 1) was developed with three patient partners (ie, individuals with lived experience of concussion) to ensure comprehensibility and suitability.

Sample size

We set a pragmatic sample size target of 30 (15 per group), considerate of resource efficiency and diminishing returns of larger samples for increasing the precision of the feasibility and efficacy estimates.

Data analysis

Quantitative data

Participants' demographics and health history data were imported from the characterisation study and summarised with descriptive statistics. Feasibility outcomes were reported as proportions for both interventions.

To estimate the effect size associated with CBT, we calculated the standardised mean difference between groups on the post-treatment MMQ-S score while controlling for pretreatment scores. Additional outcome measures are reported descriptively, by group. When participants did not answer a single item, we replaced the missing item score with the mean of answered items (n=4 for the MMQ-S and n=3 for the MCQ).

Qualitative data

We employed reflexive thematic analysis[37] to generate themes, with two trustworthiness strategies: researcher reflexivity and the involvement of multiple researchers. All interviews were audio recorded, transcribed verbatim and deidentified. Author RM used an inductive process to code and group data elements. RM then identified potential themes and integrated feedback from other authors (MR, JS and NDS) to review and refine them.

RESULTS

Feasibility measures

Recruitment occurred from November 2022 to June 2023. A total of 28 participants with confirmed FCD were offered enrolment in the study and 24 participants were randomised to CBT (n=11) or cognitive rehabilitation (n=13). See figure 1 for a participant flow diagram. To comply with the intention-to-treat principle,[38] data from participants who did not complete treatment (n=2) were included in the analyses. We were unable to invite additional participants because of limited therapist availability. Participants' baseline characteristics are reported in table 2.

Feasibility outcomes are reported in table 1 and were in the acceptable range for both the CBT and cognitive rehabilitation groups. Mean credibility ratings were similar between the CBT (M=6.7, SD=1.4) and cognitive rehabilitation (M=7.2, SD=1.2) groups. Two participants from the cognitive rehabilitation group terminated treatment early (one after 4 sessions and one after 11 sessions). Therapist adherence results were based on 52 audited sessions (~20% of 264; 27 CBT and 25 cognitive rehabilitation sessions). Although the required content was well covered, proscribed behaviours occurred in 2 (7.4%) CBT sessions and 3 (12.0%) cognitive rehabilitation sessions. The CTRS subscale measuring CBT-specific skill coverage was higher for CBT sessions (M=25.92, SD=4.34) than for cognitive rehabilitation sessions (M=2.60, SD=4.84). In contrast, the CTRS general therapeutic skills subscale was similar between groups (M=27.59, SD=4.30) for CBT vs M=28.24, SD=2.73) for cognitive rehabilitation.

Outcome measures

Figure 2 shows the primary outcome (MMQ-S) imported from the characterisation study (completed M=1.6 months (SD=0.6) before the baseline assessment for the present study) and at all time points in the present study. There is a trajectory of improvement (higher memory satisfaction/lower concern) in both groups. The standardised mean difference between groups post-treatment, adjusting for

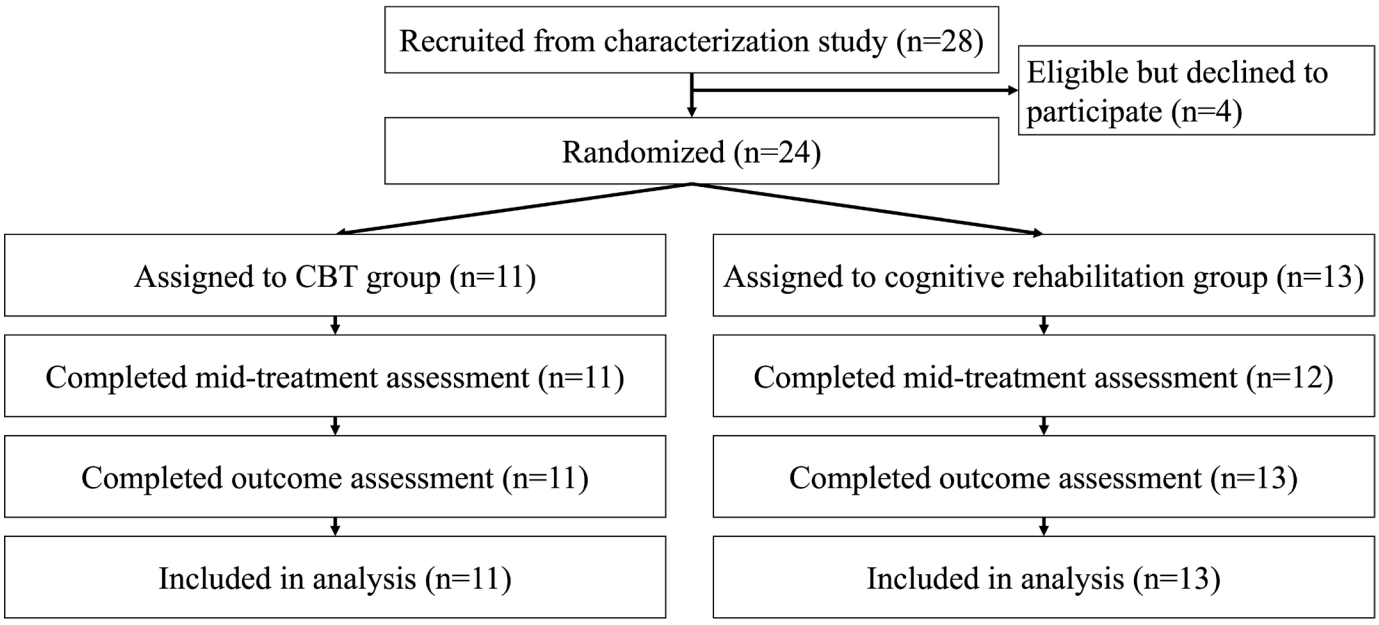

Figure 1 Participant flow diagram. CBT, cognitive–behavioural therapy.

pretreatment scores, was −0.05 (95% CI (−0.86, 0.75)). Post-treatment MMQ-S scores fell within the normal range for 22 (91.7%) participants (n=11 of 11 for CBT; 11 of 13 for cognitive rehabilitation). PGIC was similar between groups, with nearly all participants reporting their level of satisfaction with their memory as either 'better' (n=4 for CBT; n=5 for cognitive rehabilitation) or 'much better' (n=7 in each group), and one participant in the cognitive rehabilitation group reporting no change. Descriptive statistics of secondary outcome measures are reported in table 3 and tertiary outcome measures in online supplemental table S3.

Qualitative results

Five participants who completed the CBT arm (three women and two men, mean age=31.2 years, mean-time postinjury=20.3 months) participated in a semi-structured interview. Two themes about participants' experiences with the CBT intervention were identified, namely: (1) 'reframing the monologue' and (2) 'I was in a safe space to deal with it'. The first main theme ('reframing the monologue') highlighted changes in participants' beliefs about themselves and their memory. Participants no longer believed they had memory impairment and viewed their memory lapses as normative. In the second main theme ('I was in a safe space to deal with it'), participants described favourable views of their therapist and highlighted the effectiveness of certain CBT exercises (ie, cognitive reappraisal and relaxation practices) and their ability to integrate these exercises into their daily routine. Participants also emphasised the importance of their effort/engagement and expressed appreciation for the frequency (once a week) and format (Zoom videoconference) of the intervention. The above themes are described in detail with supporting quotes in online supplemental material.

DISCUSSION

The current study evaluated the feasibility of a novel CBT intervention for individuals with FCD after concussion in a pilot randomised controlled trial. The CBT protocol was tailored to address avoidance and catastrophising, two psychological constructs hypothesised to induce and perpetuate FCD. For most feasibility outcomes, the results exceeded the predetermined acceptable range for both the CBT and cognitive rehabilitation groups. The high enrolment rate (85.7%) and retention rate (100%), together with the qualitative findings, suggest that participants found the trial methods acceptable. Participants viewed both treatment approaches as credible. These findings suggest that a phase III trial using the same study methods is feasible.

Participants improved over the course of treatment, regardless of their treatment allocation. MMQ-S scores increased by more than an SD, moving towards healthy control reference values[28] by post-treatment. Virtually all participants reported that their memory was 'better' or 'much better' overall on the PGIC (n=23 of 24) and reported normal-range memory concerns on the MMQ-S post-treatment (n=22 of 24). The qualitative data suggested that participants may have benefited from treatment ingredients that were specific to CBT (eg, cognitive reappraisal). However, measures of catastrophising and avoidance improved similarly in both groups, which does not support the conclusion that CBT and cognitive rehabilitation worked through different mechanisms.

There are several possible explanations for why CBT and cognitive rehabilitation were unexpectedly associated with similar outcomes. First, there was some overlap in the content of the CBT and cognitive rehabilitation manuals, which could have weakened the distinctiveness between the two arms. Both treatments included

Table 2 Participant baseline characteristics

	CBT (n=11)	Cognitive rehabilitation (n=13)
Gender	N (%)	
Woman	7 (64)	12 (92)
Man	3 (27)	1 (7)
Transgender	1 (9)	0
Sex at birth		
Female	8 (73)	12 (92)
Male	3 (27)	1 (7)
Indigenous		
Yes	2 (18)	0
No	9 (82)	12 (92)
Did not answer	0	1 (8)
Race		
White	5 (46)	9 (69)
East or Southeast Asian	3 (27)	3 (23)
Biracial	3 (27)	1 (8)
Education		
High school graduate or less	1 (9)	0
Some college, no degree	3 (27)	3 (23)
Diploma or associate degree	3 (27)	3 (23)
Bachelor's degree or higher	5 (46)	6 (46)
Mechanism of injury		
Motor vehicle accident	5 (46)	2 (15)
Fall from standing	1 (9)	4 (31)
Sport/recreation	4 (36)	3 (23)
Assault	0	1 (8)
Other	1 (9)	3 (23)
Witnessed loss of consciousness		
Yes	3 (27)	3 (23)
No	8 (73)	10 (77)
Preinjury psychiatric history*		
Depression (yes)	3 (27)	7 (54)
Anxiety (yes)	2 (18)	7 (54)
Comorbid psychiatric conditions†		
Major depressive disorder (yes)	1 (9)	3 (23)
Generalised anxiety disorder (yes)	3 (27)	5 (38)
Panic disorder (yes)	2 (18)	5 (38)
Post-traumatic stress disorder (yes)	1 (9)	4 (31)
Substance use disorder (yes)	2 (18)	2 (15)
Non-study care received‡		
Pharmacological treatment for mental health	1 (9)	3 (23)
Psychologist or counsellor	2 (18)	6 (46)
Physical therapist	1 (9)	2 (15)
Other§	0	3 (23)
	Mean (SD)	
Age (years)	34.2 (11.7)	46.8 (10.5)
Time since injury at baseline (months)	16.5 (6.0)	17.7 (3.8)

*Self-reported, based on the question 'Prior to your injury, were you ever diagnosed with or treated for…?'.
†Assessed by the study neuropsychiatrists using the Mini International Neuropsychiatric Interview V.7.0.2, a structured diagnostic interview based on the Diagnostic and Statistical Manual of Mental Health Disorders, Fifth Edition.
‡Self-reported post-treatment, based on the question 'Since the beginning of your participation in the study, have you received…?'
§Chiropractor, massage therapist and neurofeedback.
CBT, cognitive–behavioural therapy.

education on the role of attention in memory lapses, which may have reduced symptom-related threats and facilitated acceptance of symptoms.[39] These overlapping elements may have been more potent treatment ingredients than anticipated. Second, although therapist compliance with the treatment manuals was generally good, it fell just short of our feasibility benchmark, with all essential content covered in 92% (vs 95% target) of sessions. More concerning was evidence of overt contamination in ~10% of sessions, in which the therapist covered content more compatible with the non-assigned treatment approach. Debriefing with the therapists confirmed that they found it challenging to switch between CBT and cognitive rehabilitation approaches. The CTRS data confirm that therapists were successful in using a CBT style in the CBT arm and not in the cognitive rehabilitation arm. Nevertheless, non-adherence may have further weakened the distinctiveness of the two treatments. Third, it is possible that apparent 'treatment gains' merely reflected maturation bias (natural recovery). We consider this unlikely because participants had very chronic memory symptoms at the time of enrolment (M=15.5 months after concussion) and there was no trend for improvement between the characterisation study and enrolment in the present study M=1.6 (SD=0.6) months later (figure 2). Fourth, placebo effects could explain why participants improved similarly with equally credible treatments.[40] Fifth, cognitive rehabilitation may have previously unrecognised mechanisms of benefit that resemble CBT. The two treatments have somewhat opposing philosophies. CBT aims to improve participants' confidence in their (intact) memory abilities by gradually resuming normal use and phasing out unnecessary compensatory strategies, whereas cognitive rehabilitation encourages the use of memory aids to compensate for memory impairment. Nevertheless, supporting patients to effectively use compensatory

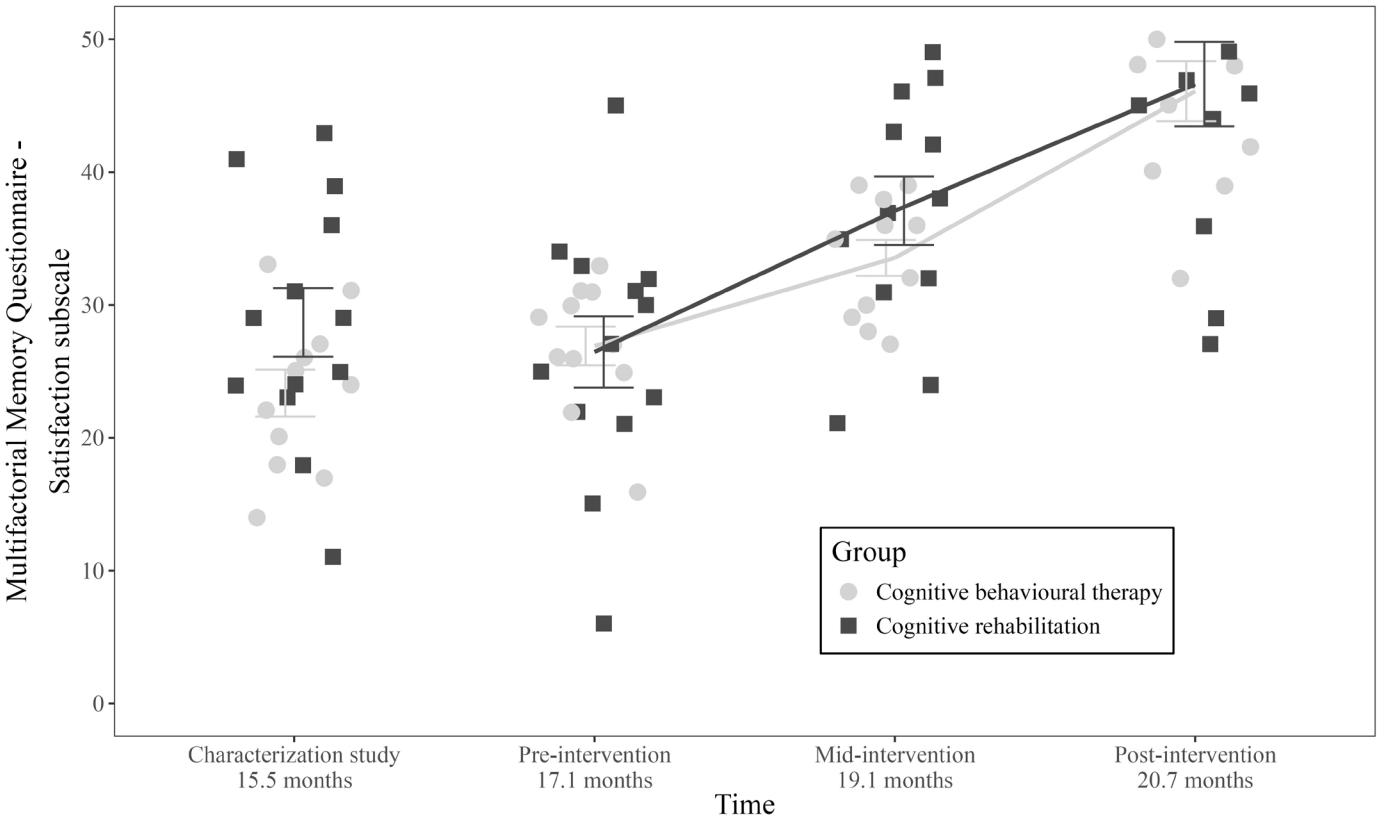

Figure 2 Multifaceted Memory Questionnaire-Satisfaction subscale scores by group.

strategies may have empowered them to increase their engagement in previously avoided activities and situations while minimising the risk of memory lapses. Finally, given the small sample, randomisation may have not achieved adequate group balance on measured and unmeasured confounders.

Limitations

Estimates of recruitment, fidelity, adherence, retention, compliance and efficacy were based on a modest sample size. Most participants (n=22) completed a prior research study[20] in addition to the FCD characterisation study. This recruitment strategy may have

Table 3 Quantitative outcome measures

Time	Characterisation study		Pretreatment		Post-treatment	
Group	CBT (n=11)	Cognitive rehabilitation (n=13)	CBT (n=11)	Cognitive rehabilitation (n=13)	CBT (n=11)	Cognitive rehabilitation (n=13)
	Mean (SD)					
MMQ-Satisfaction	23.4 (5.9)	28.7 (9.3)	26.9 (4.8)	26.5 (9.7)	46.1 (7.5)	46.6 (11.5)
FAM-Avoidance	23.7 (4.2)	19.5 (5.1)	24.6 (3.9)	23.3 (4.9)	19.6 (5.1)	19.9 (6.5)
MCQ-External	22.4 (1.7)	22.9 (1.9)	22.9 (1.6)	23.6 (1.2)	22.5 (2.2)	23.0 (2.4)
MCQ-Relative	13.9 (1.6)	14.5 (1.9)	14.7 (2.2)	15.2 (2.6)	14.3 (1.7)	14.4 (1.9)
SCS	14.8 (8.6)	9.1 (9.6)	15.5 (7.9)	14.2 (11.1)	8.6 (8.7)	5.9 (6.6)
Bothersomeness*	–	–	4.6 (1.5)	4.8 (1.7)	3.4 (2.0)	2.9 (2.0)
	N (%)					
Normal-range MMQ-S score†	2 (18.2)	5 (38.5)	4 (36.4)	6 (46.2)	11 (100.0)	11 (84.6)

*Bothersomness one-item scale.
†According to normative reference values from the MMQ Manual.[30]
CBT, cognitive–behavioural therapy; FAM, Fear-Avoidance of Memory Loss Scale; MCQ, Memory Compensation Questionnaire; MMQ, Multifactorial Memory Questionnaire; SCS, Symptom Catastrophising Scale.

introduced selection bias and restricted the extent to which certain findings (enrolment and retention rates) can be generalised. The present study was not designed or powered to determine efficacy. Future research should also investigate whether or not patients with a favourable treatment response continued to meet diagnostic criteria for FCD.

CONCLUSION

The present study is one of the first to investigate potential treatments for FCD and the first for FCD after concussion. Feasibility was strong across most criteria, but contrary to our expectations, the CBT and cognitive rehabilitation groups reported similar improvements across the primary and secondary outcome measures. This feasibility trial was useful for identifying changes that could strengthen the design of a larger, more definitive clinical trial of the CBT and cognitive rehabilitation interventions focused on testing their efficacy. For example, the results highlight the importance of including one or more credible comparison groups to control for placebo effects. Given the challenges with therapist adherence to the treatment protocols and resulting contamination, future trials should consider having different therapists for each treatment arm. Importantly, the present study suggests that FCD is a treatable condition.

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Competing interests JL received a Michael Smith Scholar Award. DLP has received honoraria for continuing medical education lectures; royalties from Springer for a textbook and honoraria from Elsevier for another textbook; is on the editorial boards of Brain and Behavior (paid), Epilepsy & Behavior, The Journal of Neuropsychiatry and Clinical Neurosciences, and Cognitive and Behavioral Neurology; receives funding from the Sidney R. Baer Jr. Foundation and NIH unrelated to this work and is on the FND Society Board, American Neuropsychiatric Association Advisory Council and the FND Hope International Medical Advisory Board. NDS has received research funding from the Canadian Institutes of Health Research, Canada Foundation for Innovation, Ontario Brain Institute, Weston Brain Institute and VGH+UBC Hospital Foundation. He has also received honoraria for continuing medical education lectures.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by the UBC Clinical Research Ethics Board (ID H22-00436). Participants gave informed consent to participate in the study before taking part.

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