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Examining effectiveness of tailorable computer-assisted therapy programmes for substance misuse:

Programme usage and clinical outcomes data from Breaking Free Online

ABSTRACT

Rationale: When evaluating complex, tailorable digital behavioural interventions, additional approaches may be required alongside established methodologies such as randomised controlled trials (RCTs). Research evaluating computer-assisted therapy (CAT) programme for substance misuse, Breaking Free Online (BFO), is informed by Medical Research Council (MRC) guidance recommending examining 'mechanisms of action' of individual intervention strategies, which is relevant when evaluating digital interventions with content that may evolve over time.

Aims: To report findings from examination of mechanisms of action of tailoring advice within the BFO programme and outcomes from specific intervention strategies.

Methodology: Analysis of variance and linear regressions were used to assess intervention completion data, and psychometric and clinical outcomes, for 2311 service users accessing drug and alcohol treatment services across the UK.

Results: Tailoring advice provided to users appeared to prompt them to prioritise completion of intervention strategies associated with their areas of highest biopsychosocial impairment. Completion of specific intervention strategies within BFO were associated with specific clinical outcomes, with a dose response also being found. Mechanisms of action analyses revealed the primacy of cognitions, with cognitive restructuring strategies being associated with improvements in mental health, severity of substance dependence, quality of life and global biopsychosocial functioning.

Conclusions: The MRC framework provides an evolved research paradigm within the field of digital behavioural change. By assessing baseline profiles of need, BFO can target the most appropriate clinical content for individual users. Mechanisms of action research can be used to inform modifications to BFO to continually update clinical content and the technology platform.

KEYWORDS

computer-assisted therapy; cognitive-behavioural therapy; mechanisms of action;
substance use disorder; recovery

1. INTRODUCTION

The literature demonstrates the advantages of tailoring interventions to the needs of the individual (e.g. Krebs et al., 2010; Lustria et al., 2013; Noar et al., 2007), with one means of delivering such interventions being through computer-assisted therapies (CAT), which are effective for delivering treatments for mental health difficulties (Espie et al., 2014; MacGregor et al., 2009; Richards et al., 2002; Williams & Whitfield, 2001) including depression and anxiety (National Institute for Health and Care Excellence, 2009) and substance use disorders (SUD) (Campbell et al., 2014; Carroll et al., 2009; Kay-Lambkin et al., 2011; Kay-Lambkin et al., 2012).

CAT programmes enhance treatment fidelity (Carroll & Rounsaville, 2010; Carroll, 2013), are cost-effective (Hedman et al., 2012; McCrone et al., 2004; Olmstead et al., 2010), and allow users to access intervention content they perceive themselves to need through being modular (e.g. Carroll et al., 2008; Elison et al., 2015b; Espie et al., 2013; Kay-Lambkin et al., 2009; Williams & Whitfield, 2001). However, this tailorable delivery format suggests the need for approaches to evaluation other than randomised controlled trials (RCTs).

One CAT programme with an alternative evaluation approach is the Breaking Free Online (BFO) treatment programme for SUD (Elison et al., 2015a, 2015b). Clinical outcomes and programme usage data are collected from users, allowing examination of associations between completion of intervention strategies and specific outcomes. This paper demonstrates an alternative approach to evaluation of tailorable CAT interventions using usage and clinical outcomes data from BFO.

1.1. Evaluating effectiveness of complex, tailorable digital behavioural interventions

Effectiveness of CAT programmes has been assessed via RCTs (e.g. Carroll et al., 2008; Espie et al., 2014; Proudfoot et al., 2004), though there is growing literature suggesting additional methodologies may be required (e.g. Craig et al., 2008; Kaptchuk, 2001; Mohr et al., 2015; Padian et al., 2010; Victora et al., 2004). Evaluation via RCT may impose methodological limitations when content is tailored to the individual (Krebs et al., 2010; Lustria et al., 2013; Noar et al., 2007), as within-group variation in personalised intervention strategies implies that assumptions of within-group homogeneity may not be met (Caldwell & Welton, 2016; Craig et al., 2008; Danaher & Seeley, 2009), which are normally required to ensure that observed changes represent a treatment effect, and not an artefact of within-participant differences at baseline (Altman & Bland, 1999; Higgins et al., 2011; Wood et al., 2008).

Consequently, there are suggestions that specific intervention strategies, or ‘behavioural change techniques’ (BCTs: Michie et al., 2008; Michie et al., 2013), should be a focus of investigation (Mohr et al., 2015). The Medical Research Council (MRC) framework for the evaluation of complex interventions (Craig et al., 2008; Moore et al., 2015) accommodates this approach. It describes a continual cycle of evaluation, exploration of mechanisms of action, and examination of barriers and to implementation, where digital interventions are perceived as ‘disruptive’ within existing healthcare systems (Christensen et al., 2006; Hwang & Christensen, 2008).

1.2. Evaluation of the Breaking Free Online treatment and recovery programme for substance misuse

An MRC-framed evaluation of BFO was initiated in 2012 (e.g. Dugdale et al., 2016a; Elison et al., 2015c; Elison et al., 2015b, 2015a), with individual intervention strategies being conceptualised using the Michie et al., (2013) BCT taxonomy (Dugdale et al., 2016b). These intervention strategies are located on the six-domain biopsychosocial ‘Lifestyle Balance Model’ (LBM: Davies et al., 2015), based on the five-factor model in cognitive-behavioural therapy (Greenberger & Padesky, 1995; Williams & Chellingsworth, 2010). The LBM (Figure 1) comprises; ‘negative thoughts’, ‘emotional impact’, ‘unhelpful behaviours’, ‘difficult situations’, ‘physical sensations’, and ‘lifestyle’. Each domain of the LBM corresponds to a module in the BFO programme which contains a psychoeducation and an ‘action’ strategy to facilitate behaviour change.

Figure 1: The Lifestyle Balance Model

A corresponding psychometric assessment, the Recovery Progression Measure (RPM: Elison et al., 2016), measures treatment-related changes in the six aspects of functioning in the LBM. Levels of impairment on each aspect of functioning, based on RPM scores, is depicted via a traffic-light system, with green, amber and red, indicating 'little', 'moderate' and 'significant' impairment respectively. Tailored advice then guides the user to concentrate on completing intervention strategies aligned to aspects of functioning with the greatest levels of impairment (amber and red domains of the LBM). Users are also encouraged to practice and rehearse interventions within green areas to help build long-term resilience. The RPM is embedded within a battery of assessments measuring substance dependence, quality of life, and depression and anxiety. Users complete this periodically, with clinical outcomes data automatically captured on a database, alongside data on how many times participants completed individual intervention strategies.

1.3. Aims

This paper reports on BFO usage and clinical outcomes data. Specific research questions include:

1. Does level of impairment on LBM domains predict which intervention strategies are completed, i.e. do users follow the tailoring advice provided by the programme?
2. Are clinical outcomes for users associated with the number of intervention strategies completed, i.e. is there a 'dose effect'?
3. What are the mechanisms of action of specific intervention strategies, i.e. is completion of specific strategies associated with specific clinical outcomes?

2. METHOD

2.1. Design

Completion of specific intervention strategies within BFO were examined in association with tailored advice and clinical outcomes.

2.2. Participants

Participants were 2311 individuals being treated for SUD in Scotland, Wales and England, between May 2014 – May 2016 and were recruited by practitioners and peer mentors providing support in

these settings. Recruitment occurred in the following settings: 1973 participants (85.4%) in specialist community-based substance misuse services; 53 (2.3%) in inpatient detoxification settings; 165 (7.1%) in prisons; and 120 (5.2%) in community mental health services.

2.3. Procedure

Participants set-up a BFO account and completed the baseline assessment with support from a practitioner or peer mentor if preferred. The baseline assessment contained the following:

- a) Recovery Progression Measure (RPM: Davies et al., 2015; Elison et al., 2016; Elison et al., 2017): contains 6 eleven-point Likert scales (i.e. 0-10) measuring levels of functioning in the six aspects of biopsychosocial functioning in the LBM. Cut off scores for levels of impairment are; 0 – 2 = ‘green’, i.e. minor impairment, 2 – 6 = ‘amber’, i.e. moderate impairment, 7 – 10 = ‘red’, i.e. significant impairment.
- b) Five items (1, 2, 17, 18, 20) from the WHO Quality of Life measure (WHOQoL-BREF: Skevington et al., 2004).
- c) Patient Health Questionnaire (PHQ-4: Kroenke et al., 2009): a 4-item scale measuring levels of depression and anxiety.
- d) Severity of Dependence Scale (SDS: Gossop et al., 1995): a 5-item scale measuring substance specific severity of dependence.

Following baseline assessment, participants were provided with access to BFO and the intervention strategies contained within it. These intervention strategies are located in BFO within six modules, each representing the six domains of biopsychosocial functioning in the LBM. Each module in BFO contains a psychoeducation strategy and an ‘action’ intervention strategy to address the corresponding domain of functioning in the LBM. To fully complete one of the six LBM modules, both the corresponding psychoeducation strategy and action strategy in the module must have been completed at least once each.

The ‘negative thoughts’ action strategy is a cognitive restructuring exercise to support users to challenge common cognitive distortions. The ‘emotional impact’ action strategy is a mindfulness-

based exercise to enable users to calm down from states of heightened physiological arousal. The 'unhelpful behaviours' action strategy is a behavioural activation exercise. The 'difficult situations' action strategy includes a relapse prevention strategy that supports users to identify situations where they might be at risk of using substances. The 'physical sensations' action strategy is a mindfulness-based exercise to reduce cravings, and the 'lifestyle' action strategy takes users through a goal-setting exercise.

The psychometric assessment was repeated a mean of 8.2 weeks (SD 10.58) from baseline. Figure 2 demonstrates how data are used by the BFO programme, and the sequence of events related to the procedure for this study. Ethical approval had previously been granted for research use of BFO data (Research Ethics Committee Reference 12/LO/0076, date of approval 16.05.2012).

Figure 2: Flow chart depicting how Breaking Free Online uses Recovery Progression data

2.4. Analyses

Bootstrapped (x10k) analysis of covariance (ANCOVA) was conducted to examine associations between levels of impairment in the six domains of biopsychosocial functioning in the LBM and the number of times participants completed intervention strategies, controlling for age and gender, as

some participants completed the same intervention strategies multiple times. Clinical outcomes were examined using repeated-measures ANOVAs. Linear regression models, controlling for baseline scores, tested for associations between the number of strategies completed, and clinical outcomes. Regression models were also used to examine the extent to which completion of strategies across the LBM modules more generally were associated with specific clinical outcomes, and to determine mechanisms of action of the programme, by examining whether completion of strategies in each of the specific LBM modules was associated with specific clinical outcomes.

3. RESULTS

Participants were 55% male and 45% female, mean age was 42.2 years (range 15 – 76 years, SD 11.5). The majority were White-British (95.2%), the remainder being Asian/Asian-British (1.2%), Black/Black-British (.8%), Mixed-race (2.4%) or of unspecified ethnicity (.4%). The majority reported heroin (n = 270, 11.7%), cocaine (n = 138, 6%) or alcohol (n = 113, 57.6%) as primary substance. Other substances included prescribed and substitute medications (n = 189, 8.2%), cannabis (n = 63, 2.7%), crack (n = 77, 3.3%), amphetamines (n = 63, 2.7%), novel psychoactive substances (n = 34, 1.5%) , tobacco (n = 22, .9%) and club drugs (n = 12, .5%).

3.1. Completion of intervention strategies

Median number of LBM strategies completed was 3 (IQR = 7) and the median number of LBM modules completed was 1 (IQR = 3). Table 1 provides the proportions of participants completing each of the 12 intervention strategies and six LBM modules.

Table 1: Number and proportion of participants completing each intervention strategy

LBM module	Intervention strategy	n (%) of participants completing strategy	n (%) of participants completing both strategies in LBM module
Unhelpful behaviours	Psychoeducation	671 (29)	499 (21.6)
	Action strategy: Behavioural activation	744 (32.2)	
Difficult situations	Psychoeducation	940 (40.7)	669 (28.9)
	Action strategy: Relapse prevention	910 (39.4)	
Emotional impact	Psychoeducation	872 (37.7)	767 (33.2)
	Action strategy: Mindfulness-based CBT ¹	1043 (45.1)	
Lifestyle	Psychoeducation	715 (30.9)	547 (23.7)
	Action strategy: Goal setting	783 (33.9)	
Physical sensations	Psychoeducation	667 (28.9)	568 (24.6)
	Action strategy: Mindfulness-based CBT	830 (35.9)	
Negative thoughts	Psychoeducation	885 (38.3)	754 (32.6)
	Action strategy: Cognitive restructuring	1090 (47.2)	

Level of baseline impairment in an LBM domain (Table 2) was associated with the number of times participants completed the corresponding LBM module strategies ($F = 67.42$, $p < .0001$). Users completed intervention strategies associated with their red LBM domains significantly more frequently than their amber ($F = 45.352$, $p < .0001$) or green ($F = 12.449$, $p < .0001$) domains. No significant difference in strategy completion was identified between ‘amber’ and ‘green’ domains ($F = .824$, $p = .364$).

¹ CBT is the acronym for ‘cognitive-behavioural therapy’

Table 2: Associations between completion of intervention strategies and levels of impairment on the Lifestyle Balance Model domains with participant characteristic as covariates

Variables regressed with the number of times participants completed intervention strategies		Test statistic	p-value	95% CI
Participant age		-1.78	.076	-.008, .000
Participant gender		-4.18	< .0001	-.035, -.013
LBM domain level of impairment		5.95	< .0001	.168, .332
Post hoc comparison of groups	Green = amber	.824	.364	1.270, 1.446
	Amber < red	45.352	< .0001	1.469, 1.593
	Green < red	12.449	< .0001	1.472, 1.666

3.2. Clinical outcomes

Between baseline and follow-up, significant decreases in scores for biopsychosocial difficulties as measured by the RPM, depression and anxiety, and alcohol and drug dependence (Table 3) and significant increases in quality of life were identified (all $p < .0001$). Medium effect sizes were identified for reductions in alcohol and drug dependence, and depression and anxiety ($r = .51$, $.60$ and $.45$ respectively). Smaller effect sizes were identified for changes in scores for quality of life ($r = .33$) and recovery progression ($r = .19$ to $.39$). Adjusting for pre-treatment scores, the degree of change in psychometric scores was associated with the total number of LBM modules completed, i.e. modules of the LBM in which participants had completed both the education and 'action' strategies (all $p < .0001$).

Table 3: Pre-post treatment changes in psychometric scores and ‘dose response’ associations between number of LBM modules completed and clinical outcomes

Measure	Changes in psychometric scores					Dose response with number of LBM modules completed			
	Pre-treatment mean (SD)	Post-treatment mean (SD)	Z	p-value for change in scores	r	F	β	95% CI	p-value for dose response
RPM total	37.69 (13.48)	32.63 (15.62)	16.279	< .0001	.35	571.609	-1.334	-1.591, -1.077	< .0001
RPM unhelpful behaviours	5.90 (2.91)	5.23 (3.04)	10.669	< .0001	.23	529.078	-.203	-.254, -.153	< .0001
RPM difficult situations	6.26 (2.65)	5.45 (2.82)	13.906	< .0001	.30	373.036	-.242	-.291, -.193	< .0001
RPM emotional impact	6.84 (5.26)	5.90 (2.86)	15.986	< .0001	.33	538.415	-.242	-.290, -.195	< .0001
RPM lifestyle	5.97 (2.74)	5.42 (2.93)	8.548	< .0001	.19	452.576	-.206	-.256, -.156	< .0001
RPM physical sensations	5.99 (2.63)	4.99 (2.89)	17.359	< .0001	.36	508.180	-.193	-.241, -.144	< .0001
RPM negative thoughts	6.73 (2.59)	5.65 (2.89)	18.270	< .0001	.39	474.408	-.227	-.276, -.178	< .0001
QoL	9.17 (4.32)	10.62 (4.62)	-15.754	< .0001	.33	613.436	.376	.300, .451	< .0001
PHQ	6.52 (3.49)	5.08 (3.69)	11.669	< .0001	.45	176.743	-.312	-.447, -.177	< .0001
SDS – Drugs	8.76 (3.99)	6.25 (4.31)	14.082	< .0001	.60	122.000	-.357	-.486, -.229	< .0001
SDS - Alcohol	8.67 (4.22)	6.47 (4.43)	21.482	< .0001	.51	442.865	-.327	-.408, -.246	< .0001

3.3. Mechanisms of action

Table 4 shows associations between completion of specific LBM module intervention strategies and specific clinical outcomes. Changes in scores for depression and anxiety were significantly associated with the number of times participants completed strategies in the LBM ($F(6,2287) = 5.630, p < .0001$), specifically strategies on the 'emotional impact' ($p = .022, CI = .029, .368$) and 'negative thoughts' ($p = .037, CI = .007, .233$) modules. Changes in severity of alcohol dependence were associated with completion of some LBM strategies ($F(6,1920) = 7.424, p < .0001$), specifically 'lifestyle' ($p = .012, CI = .038, .301$) and 'negative thoughts' ($p = .009, CI = .024, .170$) modules. However, changes in scores for drug dependence were not significantly associated with the number of times participants completed strategies in the six LBM modules ($F(6,725) = 2.103, p = .051$). Change in quality of life scores was associated with the number of times participants completed LBM strategies ($F(6,2287) = 15.482, p < .0001$), on the 'negative thoughts' module ($p = .022, CI = -.147, -.012$). Changes in total recovery progression score were associated with the number of times participants completed LBM module strategies ($F(6,2287) = 21.883, p < .0001$), specifically on the 'negative thoughts' module ($p < .0001, CI = .302, .751$).

Improvements to all aspects of biopsychosocial functioning measured by the RPM were significantly associated with the number of times participants completed strategies within at least one LBM module. Improvements in ability to cope with 'difficult situations' ($F(6,2287) = 18.547, p < .0001$) were associated with the number of times participants completed strategies on the 'negative thoughts' module ($p < .0001, CI = .062, .154$). Improvements in impact of 'negative thoughts' ($F(6,2287) = 18.415, p < .0001$) were significantly associated with the number of times participants completed strategies on the 'negative thoughts' ($p < .0001, CI = .062, .149$) and 'physical sensations' ($p = .031, CI = .008, .159$) modules. Improvements in ability to cope with unpleasant 'physical sensations' ($F(6,2287) = 10.513, p < .0001$) were significantly associated with the number of times participants completed strategies on the 'negative thoughts' module ($p = .004, CI = .020, .107$).

Improvements in the impact of 'unhelpful behaviours' ($F(6,2287) = 13.523, p < .0001$) were associated with the number of times participants completed strategies on the 'negative thoughts' ($p = .004, CI = .022, .114$) and 'physical sensations' ($p = .048, CI = .001, .161$) modules. Improvements in 'lifestyle' ($F(6,2287) = 13.978, p < .0001$) were associated with the number of times participants completed strategies on the 'lifestyle' ($p = .025, CI = .012, .176$) and 'negative thoughts' ($p < .0001, CI = .038, .129$).

modules. Finally, improvements in 'emotional impact' ($F(6,2287) = 21.178, p < .0001$) were associated with the number of times participants completed strategies on the 'negative thoughts' module ($p < .0001, CI = .057, .142$).

Table 4: Associations between the number of times participants completed LBM intervention strategies and changes in psychometric outcomes measures (n = 2311)

Outcome measure	LBM module intervention strategies	t	β	P	95% CI	Overall regression model (association between outcomes and completion of all LBM modules)		
						F	df	P
QoL	Unhelpful behaviours	.488	.020	.626	-.061, .101	15.842	6, 2287	< .0001
	Difficult situations	.335	.013	.738	-.061, .086			
	Emotional impact	-1.604	-.080	.109	-.177, .018			
	Lifestyle	-1.032	-.065	.302	-.188, .058			
	Physical sensations	-1.727	-.103	.084	-.221, .014			
	Negative thoughts	-2.294	-.079	.022	-.147, -.012			
PHQ-4	Unhelpful behaviours	-1.287	-.147	.198	-.371, .077	5.630	6, 2287	< .0001
	Difficult situations	.114	.008	.909	-.135, .151			
	Emotional impact	2.294	.198	.022	.029, .368			
	Lifestyle	.557	.067	.578	-.169, .302			
	Physical sensations	.326	.036	.745	-.183, .256			
	Negative thoughts	2.086	.120	.037	.007, .233			
SDS – Drugs	Unhelpful behaviours	.239	.024	.811	-.173, .221	2.130	6, 725	.051
	Difficult situations	-.798	-.052	.425	-.180, .076			
	Emotional impact	.216	.019	.829	-.154, .192			
	Lifestyle	-.075	-.009	.940	-.232, .215			
	Physical sensations	.732	.079	.465	-.133, .291			
	Negative thoughts	4.657	.105	.098	-.019, .230			
SDS – Alcohol	Unhelpful behaviours	1.680	.072	.093	-.012, .157			
	Difficult situations	-1.551	-.063	.121	-.142, .017			

	Emotional impact	.492	.027	.623	-.080, .134	7.424	6, 1920	< .0001
	Lifestyle	2.526	.169	.012	.038, .301			
	Physical sensations	-1.862	-.120	.063	-.247, .006			
	Negative thoughts	2.603	.097	.009	.024, .170			
RPM total	Unhelpful behaviours	-.684	-.093	.494	-.361, .174	21.883	6, 2287	< .0001
	Difficult situations	-.252	-.031	.801	-.276, .213			
	Emotional impact	.545	.090	.586	-.234, .413			
	Lifestyle	1.597	.330	.110	-.075, .735			
	Physical sensations	1.465	.291	.143	-.098, .680			
	Negative thoughts	4.592	.526	< .0001	.302, .751			
RPM unhelpful behaviours	Unhelpful behaviours	-.134	-.004	.893	-.059, .051	13.523	6, 2287	< .0001
	Difficult situations	-.863	-.022	.388	-.072, .028			
	Emotional impact	1.052	.036	.293	-.031, .102			
	Lifestyle	.607	.026	.544	-.057, .109			
	Physical sensations	1.976	.081	.048	.001, .161			
	Negative thoughts	2.890	.068	.004	.022, .114			
RPM difficult situations	Unhelpful behaviours	-.679	-.019	.497	-.074, .036	18.547	6, 2287	< .0001
	Difficult situations	1.100	.028	.271	-.022, .078			
	Emotional impact	.452	.015	.651	-.051, .081			
	Lifestyle	1.939	.082	.053	-.001, .165			
	Physical sensations	-.489	-.020	.625	-.099, .060			
	Negative thoughts	4.620	.108	< .0001	.062, .154			
RPM emotional impact	Unhelpful behaviour	-1.156	-.030	.248	-.080, .021	21.178	6, 2287	< .0001
	Difficult situations	-.286	-.007	.775	-.053, .039			
	Emotional impact	1.203	.037	.229	-.023, .098			
	Lifestyle	.874	.034	.382	-.042, .110			
	Physical sensations	1.705	.064	.088	-.010, .137			

	Negative thoughts	4.618	.100	< .0001	.057, .142			
RPM lifestyle	Unhelpful behaviours	-.874	-.024	.382	-.079, .030	13.978	6, 2287	< .0001
	Difficult situations	-.435	-.011	.664	-.061, .039			
	Emotional impact	-.276	-.009	.782	-.075, .056			
	Lifestyle	2.240	.094	.025	.012, .176			
	Physical sensations	1.318	.053	.188	-.026, .132			
	Negative thoughts	3.579	.083	< .0001	.038, .129			
RPM physical sensations	Unhelpful behaviours	-.680	-.018	.496	-.070, .034	10.513	6, 2287	< .0001
	Difficult situations	.040	.001	.968	-.046, .048			
	Emotional impact	.505	.016	.614	-.046, .079			
	Lifestyle	1.232	.049	.218	-.029, .128			
	Physical sensations	1.020	.039	.308	-.036, .115			
	Negative thoughts	2.865	.064	.004	.020, .107			
RPM negative thoughts	Unhelpful behaviours	.057	.002	.955	-.051, .054	18.415	6, 2287	< .0001
	Difficult situations	-1.097	-.027	.273	-.074, .021			
	Emotional impact	-.445	-.014	.656	-.077, .049			
	Lifestyle	1.273	.051	.203	-.028, .130			
	Physical sensations	2.157	.084	.031	.008, .159			
	Negative thoughts	4.714	.105	< .0001	.062, .149			

4. DISCUSSION

This study reports on clinical outcomes and programme usage data, generated from BFO, to determine whether users of the programme followed tailoring advice, and to determine the mechanisms of action of BFO, i.e. whether completion of specific strategies was associated with specific clinical outcomes. This approach to intervention evaluation is distinct from the RCT approach, which in general attempts to demonstrate effectiveness in comparison to placebo or an alternative intervention, without examining how an intervention exerts its effects (Akobeng, 2005; Levin, 2007). Although some RCTs examine mediators of clinical outcomes from whole interventions (Lynch et al., 2008; Whittle et al., 2017), very few examine clinical outcomes for individual strategies or components within interventions.

4.1. Baseline biopsychosocial impairment and completion of intervention strategies

Analyses demonstrated that participants did follow tailoring advice from BFO, with levels of impairment on LBM domains being significantly associated with the number of times participants completed associated intervention strategies located on the corresponding LBM module. Users were found to complete intervention strategies associated with their red LBM domains significantly more frequently than their amber or green domains. However, there was no significant difference between 'amber' and 'green' in terms of the number of times participants completed intervention strategies, which may be due to users not perceiving themselves to have significant levels of impairment in any domain unless it is shown to be red, with users perceiving amber and green domains as those in which they are functioning fairly well.

4.2. Strategy completion, outcomes and mechanisms of action

Reductions were seen in scores related to depression and anxiety, and drug and alcohol dependence, significant increases were seen in scores for quality of life, and reductions were identified in recovery progression scores. Changes in scores had small effect sizes, apart from changes in scores for severity of dependence to drugs and alcohol, with both having moderate effect sizes. A 'dosage effect' was also identified indicating that the greater the number of intervention strategies completed, the greater the improvement in functioning, concurring with findings from a systematic review examining outcomes from digital interventions for mental health and a range of health behaviours such as smoking and physical activity (Donkin et al., 2011).

Mechanisms of action analyses indicated the number of times participants completed 'negative thoughts' cognitive restructuring LBM intervention strategies was associated with change across the all measures of biopsychosocial functioning, including severity of alcohol dependence, depression and anxiety, quality of life, and RPM scores, and changes in functioning in each of the six individual LBM domains. Cognitive restructuring has been demonstrated as being effective in addressing SUD (Beck et al., 2011; McHugh et al., 2010), depression (Neimeyer et al., 2008) and anxiety (Hofmann & Smits, 2008; Hope et al., 2010), and health behaviours such as insomnia (Geiger-Brown et al., 2015), dietary behaviours (Annesi & Marenco, 2014), physical activity (Greaves et al., 2011) and smoking (Umaru et al., 2014). Many interventions, including BFO, are cognitive-behavioural and work to challenge the 'dysfunctional beliefs' (Beck et al., 2011, pg 25) that underpin and maintain unhelpful and unhealthy behaviours. Cognitive restructuring techniques belong to a class of cognitive change techniques that challenge such dysfunctional beliefs. Additionally, the widely used behavioural change theories place cognitions as central to the process of behavioural change (Taylor et al., 2006).

Although completion of the cognitive restructuring strategy in BFO was related to all clinical outcomes, this does not necessarily mean the other strategies are redundant. Complex interventions like BFO contain many intervention strategies, or BCTs, and some of these BCTs may be considered to be hierarchically higher order (Cane et al., 2015). However, these higher order BCTs may not produce an effective intervention on their own, rather, it may be interaction or mediation effects of these higher order BCTs, such as cognitive restructuring, with lower order BCTs. For example, although cognitive restructuring may 'kick start' the process of behavioural change by changing the thoughts and beliefs that underpin behaviour, it may be other BCTs, such as reinforcement and rehearsal, that may maintain any behavioural change achieved.

Indeed, intervention strategies in BFO other than cognitive restructuring, were associated with changes in specific aspects of functioning, which would confirm the notion that higher order BCTs such as cognitive restructuring are not sufficient on their own in a complex intervention. 'Emotional impact' mindfulness-based (Allen et al., 2009; Baer, 2015) strategy completion was associated with reduced depression and anxiety. Research suggests that mindfulness-based approaches are effective in the treatment of SUD (Bowen et al., 2011; Marlatt, 1994; Marlatt et al., 2010), and can significantly reduce the severity of emotional difficulties such as those associated with depression (e.g. Kenny & Williams, 2007) and anxiety (e.g. Evans et al., 2008). Completion of the 'lifestyle' strategies was associated with reduction in alcohol dependence. The lifestyle goal-setting strategy involves a goal-setting exercise

integrating implementation intentions to strengthen goal attainment (Brandstätter et al., 2001; Gollwitzer & Sheeran, 2006) which is evidenced as being effective in SUD (Bovend-Eerdts et al., 2009; Lozano & Stephens, 2010; National Treatment Agency for Substance Misuse, 2006).

The findings discussed demonstrate the importance of the negative thoughts strategies within BFO, and also that the mechanisms of action of multi-component interventions may be more complex than assumed. Although specific intervention techniques may be included with the intention of causing specific clinical outcomes, in reality, the intended mechanisms of action of an intervention may not reflect the mechanisms that actually occur. In addition, there may be interaction or mediation effects that facilitate changes to different aspects of functioning at different time points in the intervention, e.g. cognitive change strategies earlier on may stimulate cognitive changes which initiate behavioural changes, and then reinforcement strategies to maintain this behavioural change later in the process.

4.3. Limitations

A number of limitations were identified in the study. There were marginal p-values in the analyses, suggesting value in further study with a larger sample. Data were also only available from a limited time period, so it was not possible to examine how mechanisms of action of intervention strategies may exert their effect longitudinally. By examining longer-term outcomes for individuals engaging with BFO, some of the limitations around effect sizes for clinical outcomes may also be addressed.

4.4. Conclusions

The findings from this study indicate that users of BFO follow tailoring advice provided by the programme, and that completion of specific intervention strategies within the programme was associated with specific clinical outcomes. In particular, findings reported indicate that strategies to change cognition have primacy within this specific intervention. These findings demonstrate that for complex interventions it is important not just to assess clinical effectiveness, but to understand the specific ways in which individual strategies exert their effects. Further analyses are planned, including examining how the composition of traffic light colour coding at baseline may be associated with completion of specific intervention strategies, for example, whether certain numbers of red, amber and green areas may predict how many times specific strategies are completed. In addition, a mediation analysis is planned to understand how completion of the cognitive restructuring strategy in

BFO may act as a mediator, influencing the association between completion of the other strategies and corresponding clinical outcomes.

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