Supplement 3: Intervention delivery and fidelity reviews

Section 1 in this supplement describes interventions delivered to the participants in the IBBIS anxiety and depression RCT. Section 2 describes the fidelity reviews carried out across the two IBBIS concurrent RCTs (RCT1 including anxiety and depression and RCT2 including stress-related disorders, see the study protocol for explanation).

1 Description of the delivery of interventions in the study, and delivered externally

The study protocol (published on clinicaltrials.org) and the published study design articles described the intended interventions in the respective trial arms. To describe what was delivered *de facto*, we decided to calculate the specific amounts of interventions. Some measures were pre-registered, but post-hoc we decided on further measures, in order to create a nuanced insight:

Pre-planned:

→ Self-reported at 6-month follow-up: Any use of psychotherapy-like interventions, regardless of funding source, at general practitioners, psychiatrists, psychologists, coaches, psychotherapists or group therapy.

Post-hoc we decided to describe the following parameters:

- Delivered outside the study interventions:
  - → Number of publicly funded consultations at general practitioners, psychiatrists and psychologist
  - → Use of psychiatric admissions, out-patient consultations and emergency room
  - → Use of vocational rehabilitation services: number courses and their duration.
- Delivered within the study interventions:
  - → Number of contacts and duration of treatment course with health care staff
  - → Number of roundtable-meetings, and their relative placement in the treatment
- Delivery across intervention placement:
  - → Employment consultant consultations, meetings and virtual contacts

Results are shown in **Fejl! Henvisningskilde ikke fundet.**: The table present interventions delivered to the participants between baseline and 12-month follow-up. The upper panel displays what was delivered by the IBBIS-teams (mental health care in the INT and MHC groups, vocational rehabilitation in the INT group, and none in the SAU group). The lower panel shows descriptive statistic of self-report and register data of interventions delivered to the participants from other providers than the IBBIS-team, except for employment consultant services, where numbers regarding the INT group represent the contacts from the IBBIS-teams as well as any contacts they might have had outside IBBIS (if e.g., they withdraw consent to continue in the IBBIS RCT, in which case they would maybe continue receiving employment consultation services in the municipal jobcentres, outside the IBBIS programme). Self-reported intervention delivery data included all mental health care interventions regardless of financial source and register data only publicly subsidised treatment, yet, some of it might have been only partly subsidised. The gap between the self-report data and register-based hence reflects interventions from private/non-public service providers.

Hoff A, *et al. Occup Environ Med* 2021;0:1–9. doi: 10.1136/oemed-2021-107894

	Intervention type	Measure		Intervention groups INT	MHC	SAU
Delivered **in** IBBIS	Mental health care interventions	**Sessions quantity**	Mean (SD); Median	9.6 (4.4); 10	8.8 (3.5); 10	
		Cummulated duration, minutes	Mean (SD); Median	595 (262.4); 595	540.3 (176.7); 580	
		Duration, days	Mean (SD); Median	157.4 (94.1); 142	149.7 (96.3); 132	
	Vocational rehabilitation	**EC meetings**	Mean (SD); Median	5.7 (4.5); 4		
		EC digital contacts	Mean (SD); Median	3.7 (4.3); 3		
	First RTM	**Number in CM course**	Mean (SD); Median	3 (1.49); 3.66		
	RTM quantity	**Number**	Mean (SD); Median	1.4 (1.1); 1		
Delivered **outside** IBBIS	Self-report data: Mental health care	**No treatment**	Proportion [%]	57.7	43.7	14.9
		Sessions, quantity	Mean (SD)	5.5 (4.2)	6.5 (6.2)	9.5 (6.2)
		Psychologist	Proportion [%]	12.9	17.6	44.4
		Psychiatrist	Proportion [%]	5.5	7.5	11.9
		GP	Proportion [%]	12.4	11.1	20.4
		Coach or psychotherapist	Proportion [%]	8.5	10.1	15.9
		Group therapy	Proportion [%]	3	5	8
		Other	Proportion [%]	4	5	11.4
	Register data: Mental health care	**Sessions, GP**	Mean (SD); Median	6.08 (5.39); 5	6.27 (4.58); 5	6.77 (4.69); 6
		Sessions, psychologist	Mean (SD); Median	0.36 (1.55); 0	0.21 (0.95); 0	1.42 (3.23); 0
		Sessions, psychiatrist	Mean (SD); Median	0.37 (1.57); 0	0.56 (2.21); 0	0.55 (1.79); 0
		≥ 1 out-patient psych. contact	n (proportion, [%])	29 (14.1)	21 (10.5)	26 (12.8)
		≥ 1 psych. admission	n	n/a (<5)	n/a (<5)	n/a (<5)
		≥ 1 psych. ER contact	n	0	0	0
	Register data: Vocational rehabilitation	**EC meetings** (NB: for the INT group: in IBBIS)	Mean (SD); Median	5.22 (3.05); 5	2.73 (2.13); 3	2.8 (2.22); 2
		EC virtual contacts (NB: for the INT group: in IBBIS)	Mean (SD); Median	0.91 (1.2); 0	1.76 (1.76); 1	1.69 (1.5); 1
		VR course	n (proportion [%])	25 (12.1)	66 (33)	99 (48.8)
		VR course, hours (cumulated)	Mean (SD); Median	6.51 (43.09); 0	22.71 (51.76); 0	47.26 (86.1); 0
		VR course duration, days (start-to-end)	Mean (SD); Median	4.01 (15.29); 0	21.22 (39.5); 0	35.76 (47.86); 0

Table 1: Interventions delivered from Baseline to 6-month follow-up. RTM: Roundtable-meeting; GP: General Practitioner; VR: Vocational Rehabilitation; EC: Employment Consultant; CM: Care Manager; SD: Standard Deviation; MHC: Mental health care; SAU: Service as usual; INT: Integrated intervention; ER: Emergency Room; n/a: not available (too few cases, cannot be reported due to personal data regulations)

1.1 Delivered inside the IBBIS study

Median number of sessions with a health professional was 10 in both the INT and MHC groups, spanning 132-142 days, as expected in protocol. The INT groups participants received several more employment consultant contacts with their IBBIS employment consultant than the other groups where the employment consultant contacts took place in municipalities. The median number of contacts with an employment consultant in the INT group was seven, including three digital ones. This was below our expectation as with the employment consultant during a period of seven months. *Roundtable-meetings* were conducted later in the intervention course than planned, as the first roundtable meetings per participant took place later in the course than planned (median 3rd opposed to planned 2nd care manager session). Furthermore, the number was below the estimated two meetings per participant and 13% never had one. A reason for the latter can be that they withdraw from intervention.

1.2 Delivered outside the IBBIS study

In the SAU group only 14.9 % reported having received no treatment at all, and on average 9.5 sessions (SD 6.2), which is close to the level delivered in IBBIS to the MHC and INT groups, and 44.4 % of the SAU group participants consulted a psychologist (with figures in the other groups much lower), though, registers showed that only very few

of these sessions, on average 1.43 (SD 3.23) were publicly financed, and as self-report data confirmed many other financial sources were utilized (e.g. 23.9% of the SAU group participants payed themselves, and 20.9% received employer financing). Rather few participants were during the study period referred to hospital based psychiatric services, no one visited psychiatric emergency services, and numbers too small to report were they who were admitted to a psychiatric hospital, see Table 2.

In the SAU group, participants received on average 2.8 meetings with their employment consultants, and 48.8% of them was provided a vocational rehabilitation course, yielding 47 hours per participant on average in the group. For the MHC group the numbers were 2.7 meetings, 66 % yielding 22.7 hours on average. In the INT group: 5.2 meetings (including meetings in IBBIS), and 12.1 % given courses lasting 6.5 hours on average. Yet, in all three groups, median amount of VR courses was zero, and hence less than half of the participants in each group received such.

2 Fidelity reviews of implementation degree in the IBBIS trials

2.1 Introduction

Implementation-degree of the active IBBIS intervention was investigated through fidelity reviews. Fidelity reviews were done for two reasons. Firstly, implementation was measured to ensure continuous focus on program adherence and improvement throughout the trial. Therefore, each fidelity review was followed up by a dialogue between team leaders and fidelity reviewers about action points for future implementation improvement. Secondly, fidelity reviews were done to document and benchmark implementation degree for each team throughout the trial-time. This enabled us to assess the risk of type III errors (wrongly rejecting a trial hypothesis of intervention superiority due to poor implementation),[1] which is often investigated in conjunction with RCTs.[2] This appendix addresses the latter aim of the fidelity reviews.

2.2 Method

Inspired by the fidelity review methods from *Individual Placement and Support* (IPS),[3] IBBIS fidelity reviews were designed as brief, standardized, multimethod investigations resulting in a fidelity-score on a predefined fidelity-scale.

2.2.1 Fidelity scale

The IBBIS fidelity scale was developed with 25 items measured on a Likert scale from one to five (total scale ranged from 25 to 125 points). Based on the IBBIS manuals and dialogue with intervention developers, the scale was designed to cover the most important activities in the IBBIS intervention. The scale was initially designed with six fidelity categories (organization, staff, integrated services, medical assessment, mental health care and vocational rehabilitation) that clustered similar items, see Table 2.

To benchmark the degree of implementation, three thresholds were decided on the 125-point scale:

- 74 points (49 %) or more equal fair implementation
- 100 points (75 %) or more equal good implementation
- 115 point (90 %) or more equal excellent implementation

2.2.2 Data material

Fidelity reviews were based on qualitative data material (primarily semi-structured interviews, observations and random samples of service user documents). IBBIS service users, professionals and managers were interviewed and observed. The fidelity reviews did not systematically utilize any of the data sources from the trials (e.g. self-assessment or management data). The fidelity review was conducted three times in each of the two trial sites (team city and team north).

Hoff A, *et al. Occup Environ Med* 2021;0:1–9. doi: 10.1136/oemed-2021-107894

2.2.3 Analysis of fidelity findings

To simplify the findings from the six fidelity reviews, we first reorganized the fidelity results of the six item-clusters to better fit the findings of the trial. Table 2 shows the original fidelity categories and the simplified trial categories.

Fidelity category	**Fidelity item**	**Item description**	**Simplified trial category**
Organisation	1	The IBBIS team	Integration
	2	Organizational integration	Integration
	3	Management support	Organization
	4	Team leader role	Integration
	5	Psychiatrist role	Organization
Staff	1	Case load	Organization
	2	Continuity in service	Organization
Integrated services	1	Collaboration through relational coordination	Integration
	2	Shared decision making	Integration
	3	Use of plans	Integration
Medical assessment	1	Medical assessment	Mental health care
Mental health care	1	Stepped Care	Mental health care
	2	Self-management	Mental health care
	3	Cognitive behavioural therapy	Mental health care
	4	Stress coaching	Mental health care
	5	MBSR	Mental health care
	6	Person involvement and relatives	Mental health care
Vocational rehabilitation	1	Work ability assessment	Vocational rehabilitation
	2	Voluntary disclosure	Vocational rehabilitation
	3	Ordinary work	Vocational rehabilitation
	4	Fast work focus	Vocational rehabilitation
	5	Individualized job search	Vocational rehabilitation
	6	Workplace contact	Vocational rehabilitation
	7	Collaboration with other municipal organs	Vocational rehabilitation
	8	Support beyond RTW	Vocational rehabilitation

Table 2: Fidelity items, fidelity categories and simplified trial categories

Secondly, we calculated average scores for the four simplified trial categories across time and teams. All averages were weighed according to the number of participants that were enrolled in team city and team north respectively. These weighed estimates were then converted into percentages to use the benchmarks for fair, good, and excellent fidelity.

2.3 Results

The six fidelity reviews were conducted from December 2016 to March 2018. The results are shown in Table 3.

		Team of review →	City			North		
	Fidelity item ↓	Time of review →	Dec., 2016	Sept., 2017	March, 2018	Dec., 2016	June, 2017	Dec., 2017
Organisation	1	The IBBIS team	3	2	2	4	2	3
	2	Organizational integration	3	3	4	3	3	3
	3	Management support	3	4	5	4	2	4
	4	Team leader role	1	1	4	3	4	5
	5	Psychiatrist role	4	5	5	4	5	4
Staff	1	Case load	4	4	4	5	4	5
	2	Continuity in service	4	4	4	4	4	4
Integrated services	1	Collaboration through relational coordination	2	3	4	3	4	4
	2	Shared decision making	3	4	4	4	5	5
	3	Use of plans	4	4	4	4	5	5
Medical assessment	1	Medical assessment	4	4	5	4	5	5
Mental health care	1	Stepped Care	5	5	4	5	5	5
	2	Self-management	5	4	3	5	4	4
	3	Cognitive behavioural therapy	5	5	5	5	5	5
	4	Stress coaching	4	5	5	4	5	5
	5	MBSR	4	4	5	4	3	4
	6	Person involvement and relatives	4	4	5	4	5	5
Vocational rehabilitation	1	Work ability assessment	4	4	4	4	4	4
	2	Voluntary disclosure	1	3	4	2	2	3
	3	Ordinary work	1	3	5	2	2	4
	4	Fast work focus	1	4	4	1	1	3
	5	Individualized job search	4	5	5	5	5	5
	6	Workplace contact	2	2	3	3	3	4
	7	Collaboration with other municipal organs	1	5	5	1	2	5
	8	Support beyond RTW	2	4	4	3	3	4
Total			**78**	**95**	**106**	**90**	**92**	**107**

Table 3: IBBIS fidelity results from the six fidelity reviews

The analysis of the four simplified fidelity scores showed that IBBIS mental health care was implemented with 87.8 % fidelity to the scale, whereas the IBBIS vocational rehabilitation was implemented with 56.3 % fidelity to the scale, see Table 4 4. Furthermore, integration of services was implemented 61.2 % fidelity to the scale.

Simplified fidelity category	Weighted average in percentage
Integration	61.2 %
IBBIS mental health care	87.8 %
IBBIS vocational rehabilitation	56.3 %
Organization	78.4 %

Table 4: Percentage implementation degree in simplified trial categories

2.4 Summary of fidelity results

According to the fidelity reviews, implementation degree rose throughout the trial time and was generally better in one of the teams. According to the average scores across teams and time, only the IBBIS mental health care was implemented with good fidelity, whereas the IBBIS vocational rehabilitation and integration of services were only just assessed to be implemented with fair fidelity.

3 References

1 Katz J, Wandersman A, Goodman RM, Griffin S, Wilson DK, Schillaci M. Updating the FORECAST formative evaluation approach and some implications for ameliorating theory failure, implementation failure, and evaluation failure. *Eval Program Plann* 2013; **39**: 42–50.

2 Hasson H. Intervention fidelity in clinical trials. In: Richards DA, Hallberg IR, eds. Complex Interventions in Health. An overview of research methods. New York: Routledge, 2015: 232–8.

3 Bonfils IS, Hansen H, Dalum HS, Eplov LF. Implementation of the individual placement and support approach–facilitators and barriers. *Scand J Disabil Res* 2017; **19**: 318–33.