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IBD-BOOST

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On behalf of the IBD-BOOST team

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Conflicts

- Speaker fees from: Janssen, WebMD, Medscape , Merck Pharmaceutical; Tillotts Pharma UK. Pfizer advisory board.

IBD-BOOST: improving fatigue, pain and incontinence in IBD

- NIHR Programme Grant £2.4m, 2017-2023
- Qualitative: interviews on patient priorities and IBD nurse capacity to support people on an intervention: most want online intervention
- Survey: symptoms, associations and symptom clusters
- Algorithm for IBD nurses to detect reversible causes for symptoms: treat and reassess
- Co-design online self-management programme
- RCT: online self-management package + IBD nurse specialist support vs. care as usual
- Preliminary results now available

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Desire for holistic care: see me as a person not just my IBD!

“All they ever ask is how often I poo and am I bleeding?”

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The IBD BOOST survey
(Norton Hart et al ECCO 2023)

- Online (& paper) survey
- Aim: to understand the relationship between symptoms of fatigue, pain and incontinence in IBD
- 8486 responses: in past 2 weeks 30% report fatigue, 21% pain, 54% faecal incontinence. 10.9% had all 3 symptoms
- "Definitely" want help for symptom: 56% fatigue; 42% pain; 53% faecal incontinence. 29% want help for all 3 symptoms
- A heavy symptom burden which we are not addressing well at the moment

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IBD-BOOST Optimise

- Cohort study to determine who has possibly “missed” physical causes for symptoms
- Consensus from IBD nurses and gastroenterologists on common causes and actions
- Nurse led assessment
- Patient completed checklist + postal calprotectin sample: nurse review using an algorithm
- Covid-19 meant we had to reduce to a feasibility study

OPTIMISE algorithm

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Step 1	• **Check and manage RED FLAGS (all 3 symptoms)**
Step 2	• **Review checklist responses, IBD-Control responses and faecal calprotectin result** • **Obtain clinical records if needed. If disease may be ACTIVE: follow Step 2.**
Step 3	• **If FATIGUE is present: follow Step 3**
Step4	• **If PAIN is present: follow Step 4**
Step 5	• **If URGENCY or FAECAL INCONTINENCE is present follow Step 5**
Step 6	• **Once all of these are optimised, recruit into the IBD-BOOST RCT**

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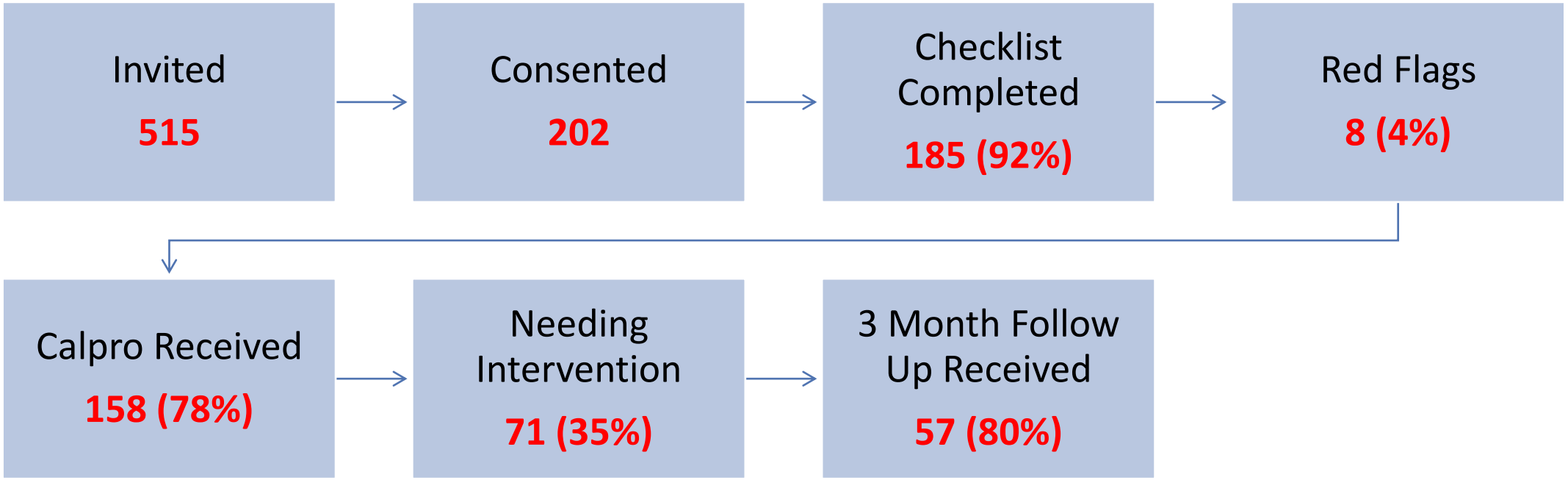
IBD-BOOST Optimise



Interviews with 3 Optimise nurses

- **Generally very positive:**
- *Tackling symptoms normally forgotten about (Nurse 2).*
- *Helps patients, helps NHS, improves quality of life (Nurse 1).*
- *Built confidence quickly (Nurse 1).*
- **Do you think it is possible to implement this algorithm into your current work?** A resounding "yes"
- *Patients really appreciate having someone go through this with them (Nurse 2)*
- *Cost and time efficient (Nurse 2)*
- *I think it's absolutely brilliant (Nurse 1)*
- *Algorithm was incredibly helpful: simple, straightforward and easy to follow (Nurse 1).*

BOOST

User Louise

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Your progress on the BOOST core sessions

100%

Active session

Summary and maintaining improvement - Continue your active session >

Goals

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Recruitment during a pandemic

- Needed 740 (actually recruited 780)
- All NHS clinics stopped recruiting (planned 20)
- Eligible: survey respondents who scored any symptom as 5 or more /10 and were interested in help
- Recruited to survey via Crohn's & Colitis UK, IBD-BioResource + social media

Primary outcomes

6-months post randomisation

- At 6-months post randomisation there was no statistically significant difference in the UK-IBDQ scores between participants allocated to the intervention (*mean* = 60.85, *SD* = 16.08) and those in the control group (*mean* = 62.09, *SD* = 14.42)
- Equally, there was no significant difference in the global rating of symptom relief scores between those participating in the intervention (*mean* = 4.13, *SD* = 2.81) and those allocated to the control group (*mean* = 3.65, *SD* = 2.75).

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Primary trial outcomes at six months post-randomisation

	Control (n=389)				Intervention (n=391)							
	Included in analysis		Unadjusted mean & SD		Included in analysis		Unadjusted mean & SD					
Outcome	**n**	**(%)**	**Mean**	**(SD)**	**n**	**%**	**Mean**	**(SD)**	**Treatment effect***	**(95%CI)**		**P-value**
UK-IBDQ	358	92.03	62.09	14.42	305	78.01	60.85	16.08	-1.674	-4.174	0.826	0.189
Global rating of symptom relief	354	91.00	3.65	2.75	305	78.01	4.13	2.81	0.438	-0.555	1.431	0.388

*adjusted treatment effect estimate

The UK IBDQ contains 30 items, each scored from 1 (i.e., best response) to 4 (i.e., worst response). The score is the sum of all individual items and ranges from 30 to 120. A higher score indicates a poorer quality of life [continuous].

GRSR: higher values are better

Secondary outcomes

6-months post randomisation

- At 6-months post randomisation into the IBD-BOOST Trial, there were no significant differences in the average pain intensity, IBD fatigue, IBD control and IBD control VAS scores between participants allocated to the intervention and those in the control group.
- However, those participating in the intervention did have a significantly lower Vaizey incontinence score (*mean* = 7.77, *SD* = 5.24) compared with the control (*mean* = 8.81, *SD* = 5.05) and a significantly higher EQ5D utility score (*mean* = 0.75, *SD* = 0.21) than the control participants (*mean* = 0.71, *SD* = 0.24).
- ***Those with IBS in IBD most likely to benefit***

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Secondary trial outcomes at six months post-randomisation

	Control (n=389)				Intervention (n=391)							
	Included in analysis		Unadjusted mean & SD		Included in analysis		Unadjusted mean & SD					
Outcome	**n**	**(%)**	**Mean**	**(SD)**	**n**	**%**	**Mean**	**(SD)**	**Treatment effect***	**(95%CI)**		**P-value**
Average pain intensity	356	91.52	2.54	2.23	305	78.01	2.37	2.15	-0.076	-0.701	0.549	0.812
Vaizey incontinence score	332	85.35	8.81	5.05	288	73.66	7.77	5.24	-0.596	-1.126	-0.065	0.028
IBD fatigue score	355	91.26	8.57	3.57	305	78.01	8.28	3.83	-0.282	-0.700	0.135	0.185
IBD control score	354	91.00	8.92	4.42	305	78.01	9.79	4.68	0.769	-0.359	1.897	0.181
IBD control VAS score	354	91.00	6.59	2.17	305	78.01	6.58	2.25	-0.001	-0.296	0.296	1.000
EQ5D utility score	344	88.43	0.71	0.24	295	75.45	0.75	0.21	0.029	0.008	0.051	0.007

*adjusted treatment effect estimate

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Complier-averaged causal effects (CACE) analysis of primary outcomes six months post-randomisation

Outcome	Included in analysis n	(%)	Effect estimate*	95%CI		P-value
UK-IBDQ						
ITT	663	85.00	-1.67	-4.17	0.83	0.19
CACE	663	85.00	-2.36	-4.44	-0.28	0.03
Global rating of symptom relief						
ITT	659	84.49	0.44	-0.56	1.43	0.39
CACE	659	84.49	0.51	-0.26	1.28	0.19

95%CI, 95% confidence interval; UK-IBDQ, UK Inflammatory Bowel Disease Questionnaire; ITT, intention-to-treat estimate (ie, primary outcome analysis model)

*CACE estimate represents the difference, on average, between compliant participants who were randomly assigned to the intervention arm and participants in the control arm who would have complied with the intervention had they been randomly assigned to the intervention arm

Compliance status in the control arm was predicted using participant age, ethnicity, education level, employment status, relationship status, and PROMIS symptom scores for pain, fatigue, & incontinence

Number of participants included in CACE analyses represents the number of participants with observed (ie, non-missing) outcome data for UK-IBDQ & Global rating of symptom relief

CACE analysis

6-months post randomisation

- In the complier-averaged causal effects (CACE) analysis of primary outcomes six months post-randomisation, UK-IBDQ scores were lower (better) for those who participated in and complied with the intervention, in comparison to those allocated to the control group (*effect estimate* = -2.36, $p = 0.03$).
- But not significant on our pre-defined significance threshold of p = 0.025 (adjusted because of 2 primary outcomes)

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BOOST team