

# A non-inferiority randomised clinical trial of the use of the smartphone-based health applications *IBDsmart* and *IBDoc*<sup>®</sup> in the care of inflammatory bowel disease patients.

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## BACKGROUND

Using smartphones to communicate symptoms and biomarkers is a potentially cost-effective and quality-of-care equivalent method for managing inflammatory bowel disease (IBD).

**Aims;** To compare the management of IBD using two smartphone apps (*IBDsmart* for symptom monitoring and *IBDoc*<sup>®</sup> for faecal calprotectin [FC] monitoring) versus standard face-to-face (F2F) care.

**Primary Aim;** Non-inferiority of quality of life (QoL) and symptoms with a reduction in standard F2F appointments in the smartphone app group.

**Secondary Aim ;** adherence and usability of the apps.

## METHODS

**Design;** 52 week prospective, multicentre, non-inferiority Randomised control trial. Recruited 6/8/2015 to 23/12/2016

**Participants: Inclusion;** confirmed UC or CD, having had  $\geq 2$  outpatient appointments and  $< 3$  disease flares in the past 12 months, being willing and able to provide written consent, and aged  $\geq 16$  years.

**Exclusion:** indeterminate colitis, severe disease requiring close monitoring, possible surgical intervention forthcoming, an ileostomy, colostomy, or ileal pouch-anal anastomosis, pregnant, unwilling or unable to provide written consent.

**Interventions:** Patients were randomized using sequential envelope to smartphone app or standard F2F.

- QoL in both groups with IBD Questionnaire (IBDQ) at 0, 3, 6, 9, and 12 months.
- The smartphone app group sent their self-reported activity index scores (Harvey Bradshaw Index [HBI] or Simple Clinical Colitis Activity Index [SCCAI]) using *IBDsmart*, and FC scores using *IBDoc* 3 monthly. App results sent to treating clinicians directly. Patients **not** seen F2F unless they flare or requested.
- The F2F care group seen as usual (at least 6 monthly) & if specifically requested.
- At 12 months the smartphone app group completed a system usability scale (SUS) for *IBDsmart* and for *IBDoc*<sup>®</sup>. Doctor usability was assessed at 12 months.

**Statistics:** For 80% power to detect non-inferiority @  $p < 0.05$ , with equivalence limit of 3, assuming standard deviation (s.d.) of 4.7 for HBI & s.d. of 3.5 in SCCAI sample size = 31 for CD and 17 for UC per group. For IBDQ, s.d. 38, then sample = 96 participants

**Clinical trial registration number:** ACTRN12615000342516

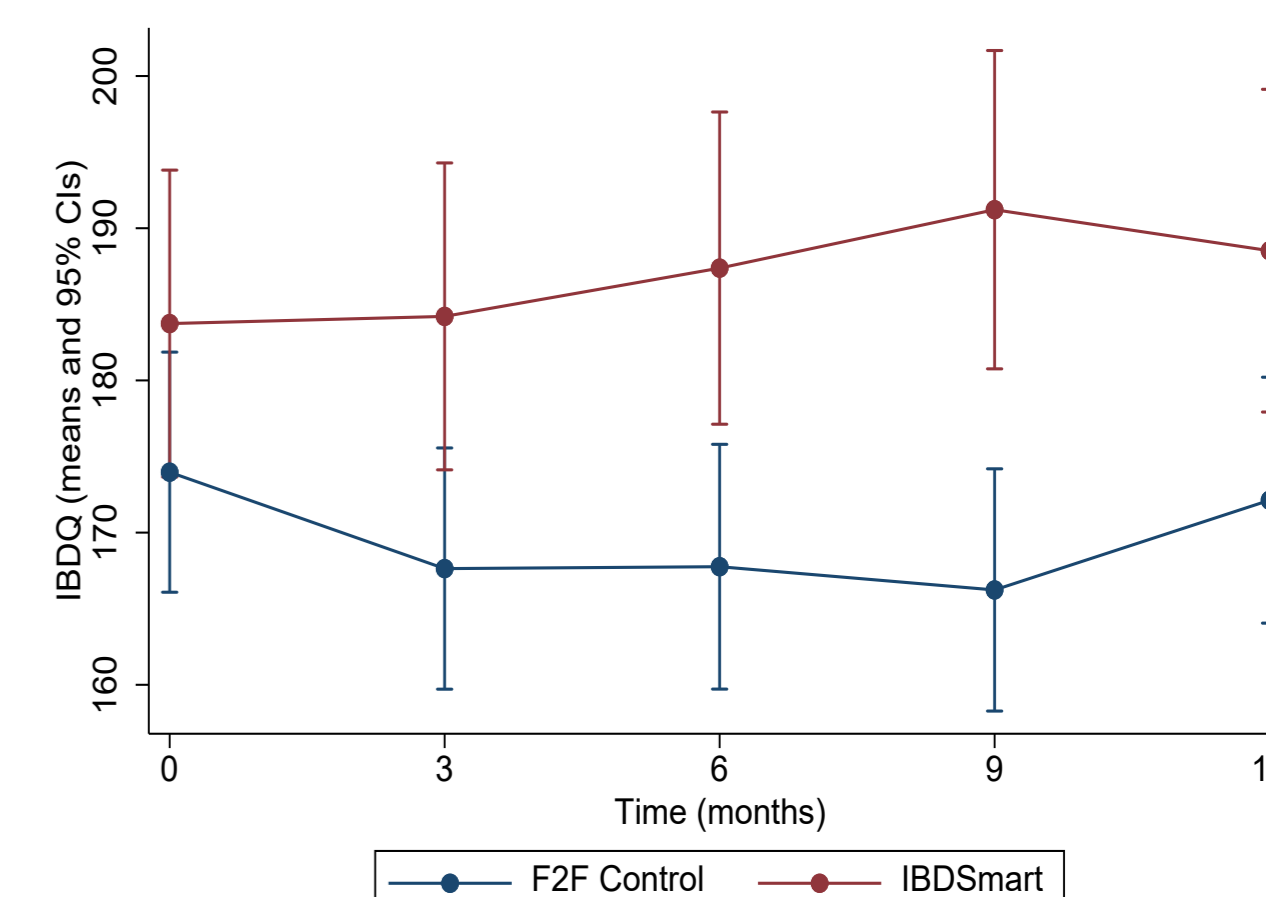
## RESULTS

107 patients were recruited. 100 (73 Crohn's disease, 49 Male, average age 35yr) completed baseline questionnaires (50 in each group). No Sig. Dif. In baseline IBDQ, HBI, and SCCAI between groups. 47 Smartphone and 49 Standard care patients completed study.

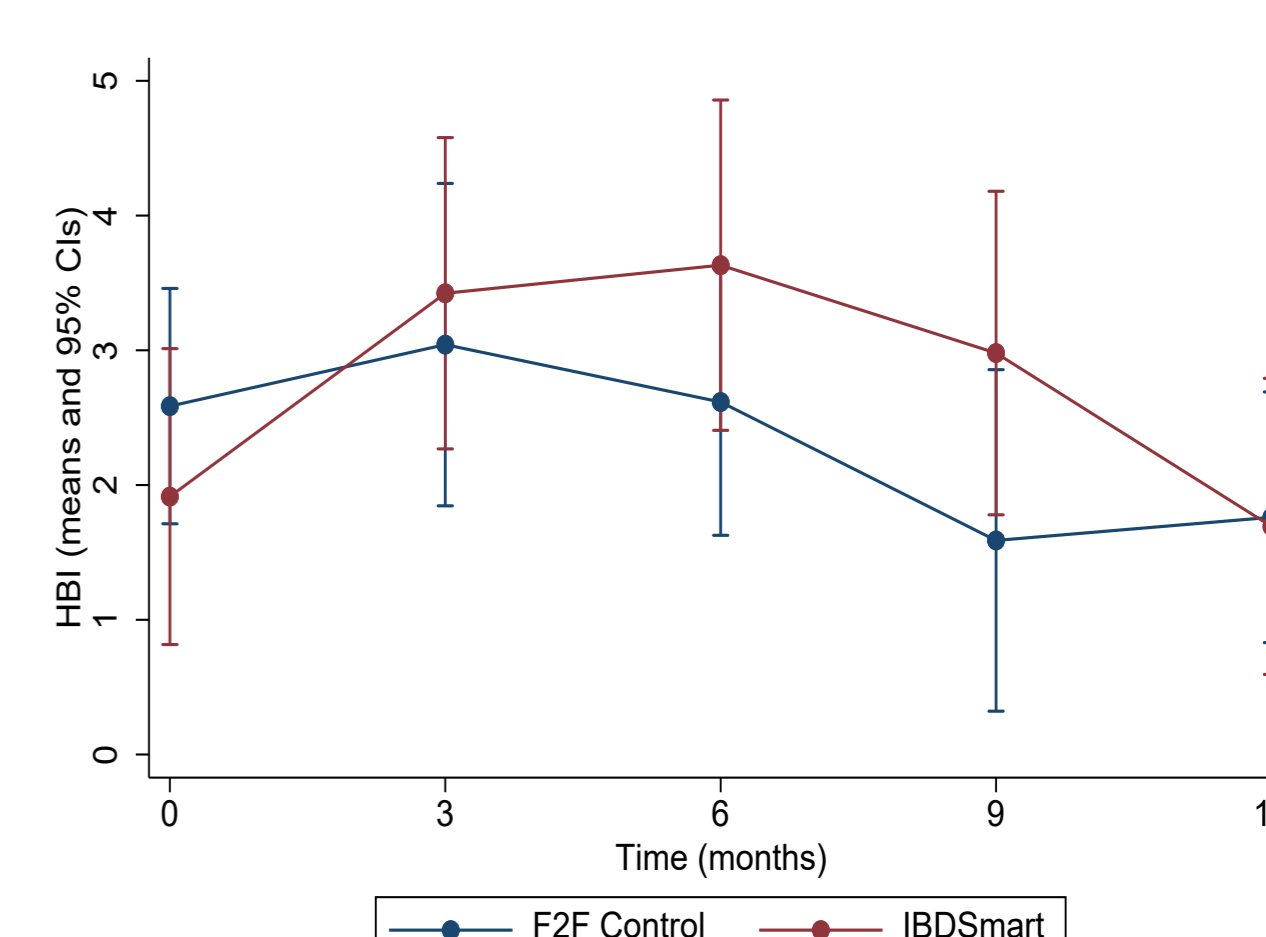
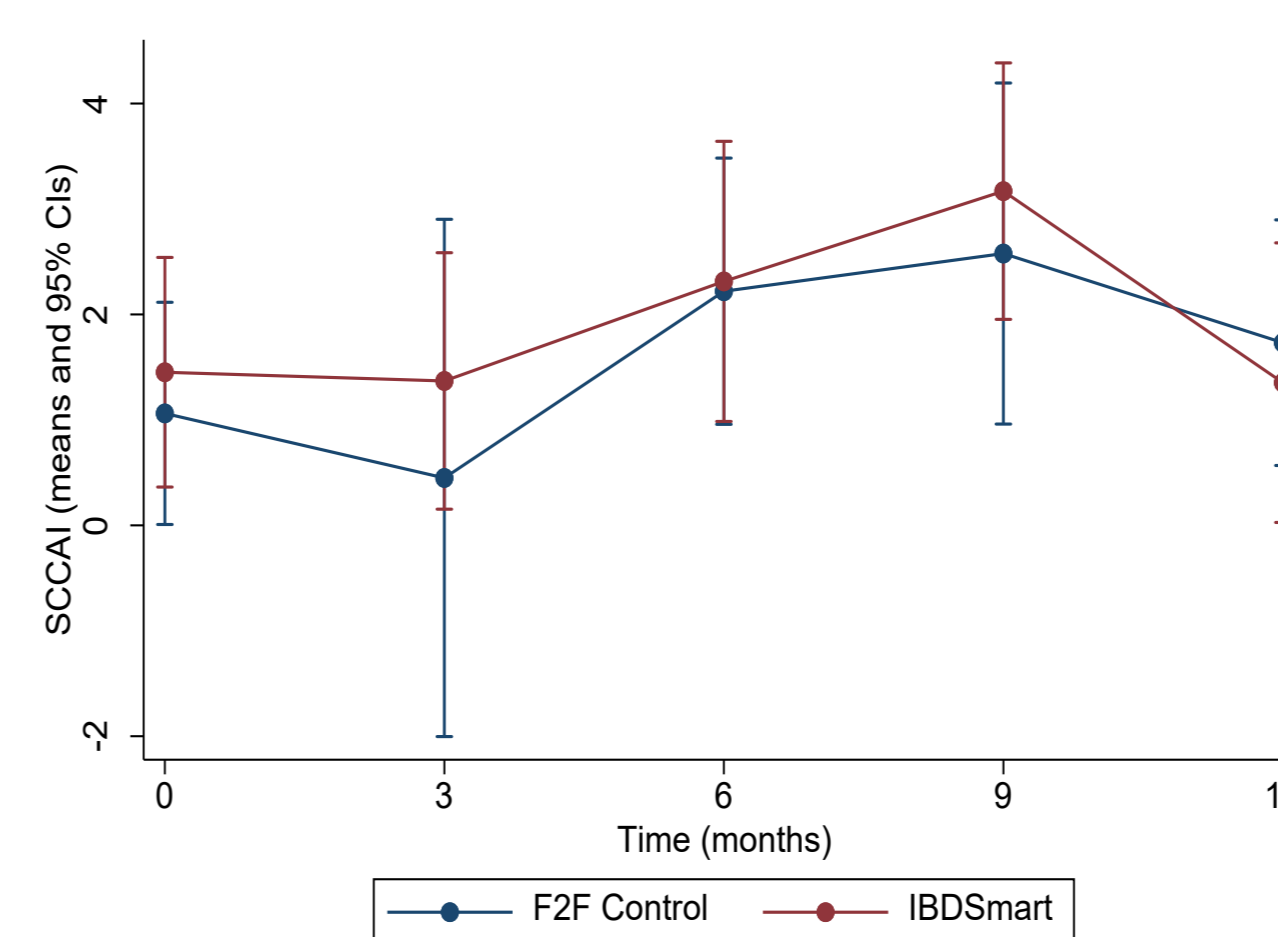
**Outpatient appointments:** 1.7(0.8) in standard F2F care cf 0.6 (0.9) in smartphone app care ( $p < 0.001$ )

**QoL:** (Per protocol)

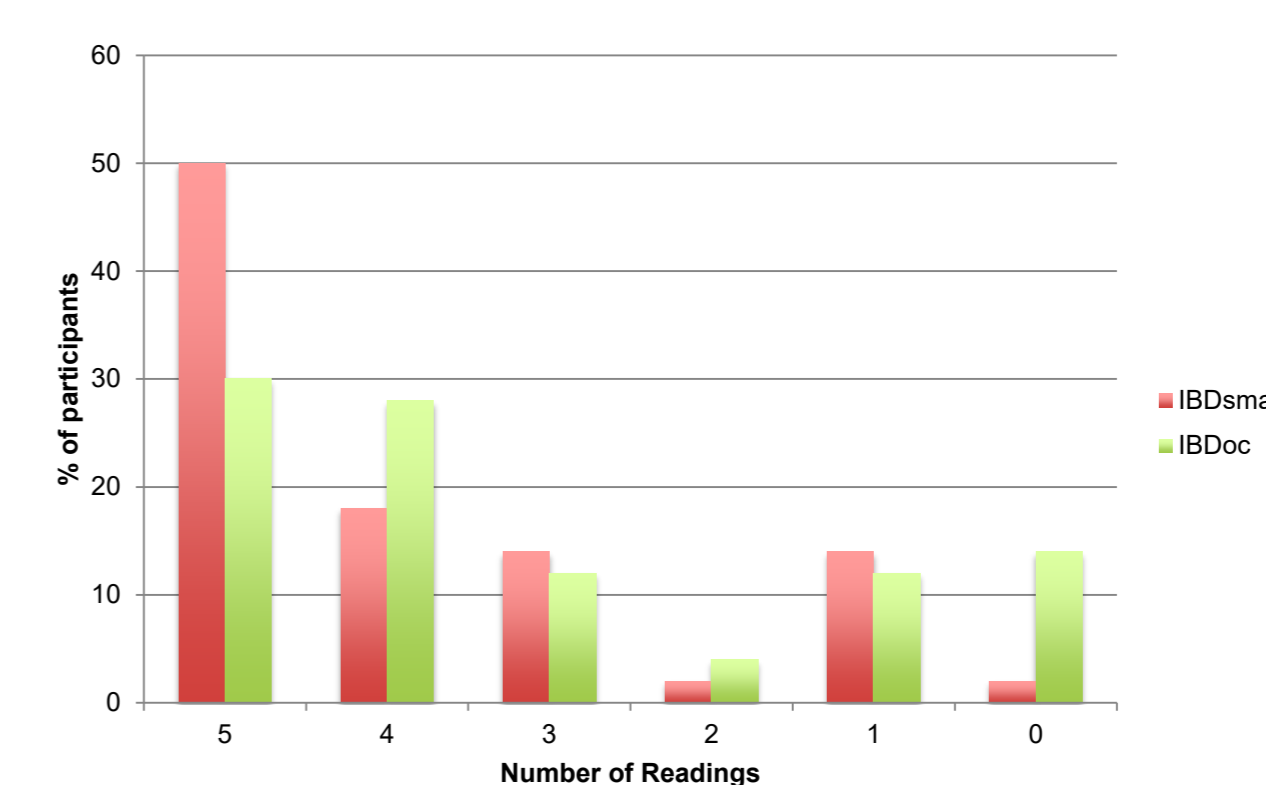
Non-inferior at all time points.



**Symptom Scores;** (Per protocol) Non-inferior except for HBI @ 6 and 9/12



**Adherence;**



**Usability;** 82% completed  $> 50\%$  of the *IBDsmart* indices; 72% completed  $> 50\%$  of the *IBDoc* tests<sup>®</sup>

- Patient-reported SUS for *IBDsmart* = 81.37 (s.d. 14.08) for *IBDoc*<sup>®</sup> = 71.6 (s.d. 16.76)
- 58% of patients felt comfortable using the apps to replace F2F appointments
- Gastroenterologist very or somewhat comfortable using *IBDsmart*/*IBDoc*<sup>®</sup> in 78% and that apps. adequately replaced F2F appointments in 58%
- In 54% gastroenterologist claimed there was something they were not able to communicate with patients via the apps, c.f. 10% with F2F.

## CONCLUSION

Use of *IBDsmart* and *IBDoc*<sup>®</sup> in routine clinical care of IBD patients over 12 months is demonstrated to be acceptable, usable, and non-inferior to standard clinic-based care.