30 November 2016

Annual report for GESA Abbvie Inflammatory Bowel Disease (IBD) Clinical Research Grant 2016

Project title: Controlled trial of a decision aid for ulcerative colitis patients: Enhancing patients’ quality of life, empowerment, quality of decision making and disease control

Revised Title: A cluster randomised controlled trial of a decision aid for ulcerative colitis patients: Enhancing patients’ quality of life, empowerment, quality of decision making and disease control

Throughout this report I will refer to the ulcerative colitis (UC) patient decision aid as “myAID” which is how we are now branding it.

1. Key project objectives achieved:

   1. Staff:
      a. Employment of Research Assistant Sasha Ruban for the myAID project: 3 days a week from 1st February 2016. Sasha is employed full time working the other 2 days on another decision aid project so is available as needed for myAID Monday to Friday.
      b. PhD Student: Andrew Kim will formally start his PhD through University of NSW on the myAID project in 2017. While not yet enrolled in his PhD, Andrew has been involved in completing the pilot project and finalising the primary and secondary outcomes of the CRCT informed by the pilot study results. He is currently writing up the pilot project results for publication. Andrew finished his gastroenterology training in 2014 as the IBD fellow at St Vincent’s Hospital Sydney. He then completed an 18 month IBD fellowship at the John Radcliffe Hospital and Oxford University in Oxford, UK with Simon Travis before returning to Australia in June 2016.

2. Pilot study: patient and clinician pilot studies completed September 2016
   a. Aims:
      i. To assess the feasibility and acceptability of myAID in routine clinical practice
ii. To inform the National Cluster Randomised Controlled Trial (CRCT) on myAID versus standard care.

b. Patient pilot study: 10 eligible ulcerative colitis patients completed all assessments for CRCT at baseline and at 2 months as well as completing a 1:1 structured interview post baseline.

c. Clinician pilot study: 15 clinicians randomised to the intervention (myAID) arm of the national CRCT viewed myAID and were interviewed about the acceptability and feasibility of the decision aid video.

d. Results:
   i. Universal positive feedback on myAID from both patients and clinicians. Patients judged myAID to be informative, well presented and easy to use. Clinicians welcomed myAID as a positive addition to their clinical practice.
   ii. At baseline all patients had:
       1. Active disease (mean SCCAI: 6.5)
       2. Reduced quality of life (AQoL-8D: 0.68)
       3. Work productivity impairment due to UC (32.7% work and 48% activity impairment)
   iii. At 2 months:
       1. Improved disease activity (SCCAI: 6.5 versus 4.4)
       2. Improved quality of decision making (Decisional Conflict Scale: 39.7 at T1 and 25.4 at T2)

e. Presentations:
   i. South West Sydney Local Health District Research Showcase October 2016
   ii. NSW Patient Experience Symposium May 2017 (abstract submitted but not yet notified if accepted)

f. Publications:
   i. First draft of paper on the pilot study due first week December 2016. Aim to submit to the journal: Inflammatory Bowel Diseases

1. National Cluster Randomised Controlled Trial (CRCT) on myAID versus standard care
   a. 14 sites recruited for the CRCT nationally (7 randomised to either standard care or intervention). This includes approximately 55 clinicians. In the original proposal the plan was to only include NSW and SA sites but it was subsequently deemed feasible to include more sites nationally. Participating sites (approximate number of clinicians): Royal Adelaide Hospital (4), St Vincent’s Hospital Victoria (2), Box Hill Hospital (6), The Alfred Hospital Melbourne (8), Monash Hospital (5), Fiona Stanley (1), Royal Brisbane Hospital (4), Mater (5), Liverpool (5), Concord (3), St Vincent’s Hospital NSW (2), St George Hospital (2), Wollongong Hospital (2), Royal Prince Alfred Hospital (1). Back up sites available if recruitment is suboptimal: Flinders Medical Centre, Blacktown Hospital, Royal North Shore Hospital, Princess Alexandra Brisbane, St John of God Subiaco, Austin Hospital.
   b. Primary and secondary outcomes revised following pilot study results and finalised August 2016.
   c. Ethics (NEAF approved on 18th October 2015). Site specific approval for each site: Liverpool (17/11/2015), Wollongong (7/9/2016), St George (19/10/2016), St Vincent’s Victoria (3/11/2016), The Alfred (31/8/2016), Royal Adelaide Hospital (3/11/2016), Royal Prince Alfred Hospital (7/11/2016), Concord Hospital (16/11/2016), Royal Brisbane Hospital (11/11/2016). Remaining sites still waiting approval (Fiona Stanley Hospital, St Vincent’s NSW, Box Hill, Monash Hospital, Mater Hospital).
   d. Roll out of CRCT (as at 30 November 2016):
i. Commencement date: 6th October 2016 at first site (Liverpool)
ii. Recruitment to 30 Nov: recruited to standard (8) and intervention (3) arms
iii. Sites initiated:
   1. October 2016: Liverpool, Wollongong, St George;
   2. November 2016: St Vincent’s Victoria, The Alfred, Royal Adelaide Hospital, Royal Prince Alfred Hospital, Concord Hospital and Royal Brisbane Hospital.
iv. Anticipated timeline of initiation of remaining sites: Fiona Stanley (Jan 2017), St Vincent’s NSW (December 2016), Box Hill (December 2016), Monash (December 2016), Mater (December 2016).

2. **Project objectives: January 2017 onwards**
   
a. National CRCT:
   i. Consolidate initiation and then ongoing active involvement of all 14 sites nationally and ensure optimised recruitment
      1. Monthly emails to all clinicians and nurses to ensure no issues. Phone calls as needed.
      2. 3 monthly newsletters outlining trial progress and also highest recruiting sites
   ii. Aim to complete recruitment of required 240 eligible UC patients by mid 2018 with all follow up completed mid 2019.
   iii. Complete ethics at back up sites and include in CRCT if recruitment suboptimal

   b. Publications:
      1. Pilot study results: aim completion for submission March 2017
      2. Outline of CRCT protocol: aim for submission July 2017

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‘Working together to provide expert individualised care for Crohn’s & Colitis’

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The myAID study group