**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**

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**Synopsis**

Shared decision making (SDM) in chronic diseases enables and encourages patients to play an active role in the management of their health. Decision Aids (DAs) are tools developed for preparing patients for decision making about specific treatment choices and are used to promote SDM. This project is being conducted to identify and assess preferences, challenges, and quality of life (QOL) in patients with Ulcerative Colitis (UC) and to test the efficacy of an internet-based DA, named my Actively Informed Decision (myAID). myAID is expected to improve medium-term QOL by better patient empowerment and quality of decision making in disease treatment and management. In turn, the intervention is expected to also improve patients’ anxiety, medication adherence, and potentially, UC disease outcomes.

This study is a collaboration of ideas between A/Prof Susan Connor, Prof Afaf Girgis, Prof Jane Andrews and Associate Professor Corey Siegel. The study will be conducted in New South Wales (NSW), South Australia (SA), Queensland (QLD), Victoria (VIC) and Western Australia (WA), and will recruit approximately 460 patients across an estimated time period of 2 years.

**Rationale**

Inflammatory bowel disease (IBD) is currently estimated to affect at least 77,000 Australians, with that number predicted to rise to over 100,000 by 2022. Just under half of IBD patients in Australia are affected by UC, with considerable cost to the health care system and the patient and significant patient burden. In 2012 costs were estimated in Australia at $3.2 billion per

annum, including $100 million related to hospitalisations, $362 million due to loss of productivity and $2.75 million related to other financial losses, of which $2.53 million was attributed to burden of disease and loss of well-being.

SDM is a model of patient centred care that enables and encourages patients to play a key role in the management of their health. SDM seeks to leverage provider expertise in light of clearly thought through and well-articulated patient values to achieve the goal of helping patients identify and decide upon medically reasonable treatments that best match their preferences. Evidence indicates that patients participating in decision making can experience more favourable health outcomes, lower demand for healthcare resources, and increasing satisfaction with their experience.

This project will include online questionnaires over a 12 months’ time period to assess and identify patient QOL, empowerment, anxiety, medication adherence and disease activity. Results from this study will be used to evaluate the effectiveness of myAID as part of the management of patients with UC. By engaging a group of patients with UC in this process, it is hoped that this process will be optimised.

**Aims**

The overall aim of the project is to improve, through the implementation of myAID, the QOL, and empowerment, quality of decision making and disease control of patients receiving treatment for UC.

The study objectives are to:

1. Pilot test myAID and study procedures in UC patients under usual clinical care.
2. Learn what outcomes (positive and negative) are most important to patients.
3. Evaluate the efficacy of the intervention (implementation of myAID) compared to usual care in a cluster randomised controlled trial (CRCT).

**Hypothesis**

myAID, an internet-based DA will help patients with UC better understand their disease and treatment options, leading to more informed treatment decisions, increased adherence to therapy, and better long-term outcomes.

H1. The intervention is acceptable to patients, as evidenced by at least 75% of intervention group participants engaging with the intervention (accessing myAID at least once).

H2. The intervention leads to enhanced QOL, empowerment and quality of decision making, reduced anxiety and improved disease outcomes.

**Participating sites**

The pilot test of myAID will be conducted at Liverpool Hospital, NSW (South West Sydney Local Health District) and the main project will be conducted collaboratively across multiple sites in New South Wales (NSW), South Australia (SA), Queensland (QLD), Victoria (VIC) and Western Australia (WA).

**Research Plan** **& Study Design**

The pilot study will test recruitment procedures and study logistics and seek feedback on myAID from a convenience sample of 10 UC patients prior to the main CRCT commencing. This will only be conducted at Liverpool Hospital, prior to commencement of the main study. A clinician interview will test the feasibility and usability of myAID in clinical practice. Feedback will be obtained through phone interviews from a convenience sample of 15 gastroenterologists that have agreed to participate in the CRCT. The clinician interview feedback will confirm the feasibility and practicality of the study logistics.

Eligible UC patients will be identified for inclusion by participating clinicians (gastroenterologists) during clinical consultation. Interested patients will be contacted by the research assistant (RA), provided with further study information, including the patient information sheet, and queries addressed. The patients will be eligible to take part in the study if they:

a) have a diagnosis of UC;

b) are 18+ years;

c) have failed or are failing 5-aminosalicylate therapy oral +/- rectal or any therapy beyond 5ASAs (failure includes non-adherence);

d) are making a new decision about therapy.

There is no UC disease extent or severity limitations. The study runs independently of decisions between patient and their consultant about treatment choices.

In the CRCT, patients interested in participating in the study will be sent an information package about the study and a unique resource locator (URL) where they will be asked to provide consent and to complete the baseline survey. Following survey completion, a separate, unique URL to myAID will be provided to those patients in the intervention arm cluster. Patients will then return to the participating consultant to discuss their decisions about further UC management.

Participants will complete study measures over a 12 month time period (see Table 1) which will consist of 5 online surveys and collection of 4 stool samples for FC.

The primary outcome measure of the study will be the patients’ QOL using AQoL (Assessment of Quality of Life)-8D.

The secondary outcome measures will include: 1. patients’ empowerment, as measured by the Health Literacy Questionnaire (HLQ) and the 4 dimensions (23 items) from the Health Education Impact Questionnaire (heiQ): *Positive and Active Engagement in Life*, *Constructive Attitudes and Approaches*, *Self-monitoring and Insight* and *Emotional Wellbeing;* 2. quality of decision making, as measured by: the Decisional Conflict Scale (DCS) (16 items), the Trust in Physician Scale (11 items), and 4 items specifically developed to assess consistency between patient choice and treatment subsequently received; 3. anxiety, as measured by the 7-item Anxiety scale of the Hospital Anxiety and Depression Scale (HADS); 4. Medication Adherence, as measured by the 8-item MMAS-8 adherence; 5. UC disease activity, as measured by the Simple Clinical Colitis Activity Index (SCCAI) and FC; 6. Clinical outcomes,

as captured through online questionnaire to determine: i) proportion of patients taking steroids; ii) proportion of patients requiring surgery; and iii) unplanned hospital admissions (UPHA); and 7. work productivity, as measured by the 6-item Work Productivity and Activity Impairment Questionnaire (WPAI).

Implementation and acceptability of myAID will be assessed for patients who have utilised myAID, at 2 weeks following their “decision-consultation”. This will be through inclusion of additional questions at the end of their usual surveys (refer to Table 1). Intervention group participants’ views will be sought regarding the ease of reviewing myAID, usefulness of its content, optimal timing for receipt of myAID and the extent to which it facilitated discussion of treatment with their consultant at the consultation two weeks previously.

**Table 1:** Timing of administration of outcome and process measures

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Outcome Measures and Consultation Timings | Baseline at 1st consultation | Decision consult (at 2-4 weeks) | Post decision consult | 2 months\* | 6 months\* | 12 months\* |
| Clinical review | 🗶 | 🗶 |  | Suggested not required | Suggested not required | Suggested not required |
| Faecal calprotectin (returned to any SONIC lab or t hospital) | 🗶 |  |  | 🗶 | 🗶 | 🗶 |
| Online survey | 🗶 |  | 🗶 | 🗶 | 🗶 | 🗶 |
| AQoL-8D | 🗶 |  |  | 🗶 | 🗶 | 🗶 |
| heiQ | 🗶 |  |  | 🗶 | 🗶 | 🗶 |
| HLQ | 🗶 |  |  | 🗶 | 🗶 | 🗶 |
| Quality of Decision Making | 🗶 |  | 🗶 | 🗶 | 🗶 | 🗶 |
| HADS - Anxiety | 🗶 |  | 🗶 | 🗶 | 🗶 | 🗶 |
| MMAS-8 | 🗶 |  |  | 🗶 | 🗶 | 🗶 |
| UC disease activity (P-SCCAI) | 🗶 |  |  | 🗶 | 🗶 | 🗶 |
| Clinical outcomes (Patient Diary) | 🗶 |  |  | 🗶 | 🗶 | 🗶 |
| WPAI | 🗶 |  |  | 🗶 | 🗶 | 🗶 |
| Implementation & acceptability (intervention group only) |  |  | 🗶 |  |  |  |
| \* = indicates time post 1st consultation | | | | | | |

Approximately 460 UC patients will be recruited from NSW, SA, VIC, QLD and WA and will complete the online surveys at the specified time points of the study either in the Gastroenterology Clinic or in their home. Personal information will not be linked to any specific survey record. All responses given by participants will be de-identified. Data from the surveys will be analysed and summarised into report forms. All results will be reported in an aggregate to protect patient confidentiality. Data will be stored on a password-protected, secure system to prevent unauthorised access.

As a way of remuneration for their time and participation in the study, all participants will be entered into a draw for a chance to win one of thirty $200 gift cards of their choice, with each completed questionnaire or FC sample counting as additional entries for that participant. The draws will be held each time a group of 80 participants complete the 6-month assessment (8 winners for each group of 80), and at the end of the recruitment for all participants completing the 12-month assessment (6 winners for all eligible participants).

**Outcomes and Significance**

The information collected from this study will be used to optimise implementation of myAID. It is expected to help patients with UC better understand their disease and treatment, lead to more informed treatment decisions, increased adherence to therapy, and better long-term disease outcomes.