**A feasibility study of a psycho-educational support intervention for men with prostate cancer on active surveillance**

Dr John G Hughes,[1] Professor Geraldine M Leydon,[2] Dr Sam Watts,[2] Stephanie Hughes,[2] Dr Lucy A Brindle,[3] Dr Emily Arden-Close,[4] Roger Bacon,[5] Honorary Associate Professor Brian Birch,[6] Dr Lallita Carballo,[7] Dr Hilary Plant,[7] Professor Caroline M Moore,[8] Associate Professor Beth Stuart,[2] Professor Guiqing Yao,[9] Professor George Lewith,[10] Professor Alison Richardson[11]

[1]Royal London Hospital for Integrated Medicine, University College London Hospitals NHS Trust
[2]Department of Primary Care and Population Sciences, University of Southampton
[3]School of Health Sciences, University of Southampton
[4]Department of Psychology, Bournemouth University
[5]Patient representative
[6]University Hospital Southampton and School of Medicine, University of Southampton
[7]University College London Hospitals Macmillan Support and Information Service
[8]Division of Surgery and Interventional Science, University College London
[9]Department of Health Sciences, University of Leicester
[10]Deceased, formerly Department of Primary Care, University of Southampton
[11]School of Health Sciences, University of Southampton and University Hospital Southampton NHS Foundation Trust

Corresponding author contact details:
Dr John Hughes
Director of Research
Royal London Hospital for Integrated Medicine, UCLH NHS Trust
60 Great Ormond Street
London WC1N 3HR
Tel: +44 (0)20 3448 8883
Fax: +44 (0)20 7391 8869
Email: John.Hughes8@nhs.net

**Abstract**
Background: PROACTIVE is a psycho-educational support intervention for prostate cancer patients managed on Active Surveillance. PROACTIVE is comprised of two interdependent components: group workshops and internet delivered information modules. We conducted a feasibility study to determine the practicality of delivering PROACTIVE at two prostate cancer centres.

Methods: The feasibility study was a mixed methods randomized parallel-group exploratory trial. Participants were randomised using a ratio of 3:1 PROACTIVE group to treatment as usual. Qualitative semi-structured interviews and quantitative measures were completed at baseline, intervention completion (week 6), and at 6-months follow-up. Interview transcripts were analysed thematically using Framework analysis. Descriptive statistics were used to examine recruitment and retention rates, and changing trends in outcome measures.

Results: Most aspects of the research design and PROACTIVE intervention were acceptable to those participating in the study. In particular participants valued the opportunity to share and discuss experiences with other prostate cancer patients on Active Surveillance, and receive detailed authoritative information. However, three issues were identified:
1. a low response rate (13 participants recruited, response rate 16%)
2. low utilisation of internet delivered information modules
3. self-perceived low levels of anxiety amongst participants with the majority perceiving their cancer as not impacting on their day-to-day life or causing anxiety.

Conclusions: Due to these significant research design issues it is not recommended PROACTIVE be evaluated in a large scale randomised controlled trial. Further research is required to explore the impact of Active Surveillance on anxiety amongst men with localized prostate cancer managed by Active Surveillance.

**Keywords:** Prostate Cancer; Active Surveillance; Anxiety; Psycho-educational Support; Feasibility Study

## Introduction

Whilst prostate cancer is the commonest cancer in men, and the second commonest cause of cancer death in men, survival after a prostate cancer diagnosis has improved markedly over the last 15 years, in part due to diagnosis at an earlier stage. Men who are diagnosed with low-risk prostate cancer are advised to undergo active surveillance (AS). The cancer can be monitored, and if signs of more aggressive disease are seen then curative treatment can be offered at that point. This approach has been developed because prostate cancer treatment can be associated with significant side effects, such as urine leakage, bowel problems and difficulties with sexual function.[1] AS involves deferring or avoiding unnecessary treatments, and instead, introducing surveillance for evidence of disease progression with biopsies, blood tests and, ideally, magnetic resonance imaging (MRI).[2] A number of international organizations have updated their guidelines to include AS as a management strategy for low-risk prostate cancer (prostate specific antigen <10ng/ml and Gleason score ≤6 and Clinical stage T1 to T2a).[2-5]

Previous studies have found varying levels of anxiety amongst prostate cancer patients managed with AS, ranging from 13% to 45%.[6] A qualitative study involving men on AS revealed two over-arching themes: problems living with AS, and the supportive care requirements of AS patients.[7] Anxiety is the most accurate predictor of low risk AS patients asking to access radical treatment without obvious clinical benefit.[8,9] Men receiving radical treatment may experience significant physical consequences with no increase in survival. Therefore tailored support interventions that enable low risk AS patients to manage anxiety are warranted. Such interventions, with the aim of supporting patients through a better understanding of the processes involved in AS and why it represents the preferred treatment approach, are hypothesized to offer an effective means of managing anxiety.

Previously published qualitative data[7] were used to develop the PROACTIVE intervention (PROACTIVE: PROstate cancer support intervention for ACTIVE surveillance). The present study explores the feasibility of delivering PROACTIVE in a two centre feasibility study.

## Methods

The study employed a mixed methods randomized parallel-group exploratory study design to determine the feasibility of delivering PROACTIVE within an NHS setting. This included preliminary data on the size of any effect and explored the views of patients about trial design and, for those allocated to the PROACTIVE intervention, their views on the intervention. Patients were recruited from the urology departments at University Hospital Southampton NHS Foundation Trust (UHS) and University College London Hospitals NHS Foundation Trust (UCLH).

Inclusion criteria were as follows:

- Low or intermediate risk prostate cancer as per NICE 2014 definition[2]
- Access to the internet
- Willing to participate and provide informed consent
- Managed by AS for less than 12 months
- No follow-up MRI subsequent to placement on AS
- Fluent English (written and oral)

- No additional cancers (including non-melanomas)
- No significant mental illness (such as psychosis)

Participants were randomized to receive either PROACTIVE or Treatment as Usual (TAU) via the LifeGuide Website.[10] Participants were randomised using a ratio of 3:1 intervention group to control group. Those allocated to TAU were provided with access to the PROACTIVE support website upon study completion.

This investigation ran for 6 months with quantitative measures completed at baseline, intervention completion (week 6), and at 6 months follow-up. Questionnaires were completed electronically via the LifeGuide website with participants prompted to do so via email reminders. Patients were also asked to participate in semi-structured interviews at the same 3 time points. Telephone interviews lasting 20-70 minutes were conducted by an experienced qualitative interviewer, audio-recorded and transcribed verbatim.

Ethical approval for the study was obtained from Oxfordshire Research Ethics Committee [reference 11/SC/0355].

***Outcome measures***

The study employed three validated outcome measures to determine their suitability to capture outcomes of interest in any future trial. The Hospital Anxiety and Depression Scale (HADS);[11] The Warwickshire/Edinburgh Mental Wellbeing Scale (WEMWBS);[12] and the Memorial Anxiety Scale for Prostate Cancer (MAX-PC).[13] A Patient Demographics Questionnaire was also used to collect relevant demographic data.

***PROACTIVE Intervention***

PROACTIVE is a psycho-educational support intervention comprised of 2 individual interdependent components, group workshops and internet modules.

*Group Workshops*

PROACTIVE involved three 2-hour group workshops facilitated by two experienced Clinical Nurse Specialists. Each workshop addressed a different topic area, consisting of:

- **Workshop 1**: Introduction and overview of AS (workshop provided participants with a detailed overview of the clinical rationale for AS and what being managed with AS involves whilst providing opportunity for group-based discussions about AS)
- **Workshop 2**: Living and Feeling Well (workshop looked at the issues associated with stress and anxiety and introduced participants to two simple to use and easy to learn breathing based relaxation techniques)
- **Workshop 3**: Wives and Partners Workshop (workshop introduced wives/partners/significant others of participants to PROACTIVE).

*Internet Modules*

PROACTIVE involved 6 weekly modules accessed through the web-based LifeGuide platform developed with the aim of complementing and extending information provided during workshops. Participants' had access to all internet modules from the start of participation. Each internet module addressed a different component:

- Week 1 Module: Information session about AS, physical activity advice
- Week 2 Module: Foods to eat, and an introduction to stress
- Week 3 Module: Relaxation and resilience techniques
- Week 4 Module: Talking to others
- Week 5 Module: Thoughts and feelings
- Week 6 Module: Daily life; money and work

***Data Analysis***

*Quantitative data*

Descriptive statistics and graphical representations of quantitative data were used to examine recruitment and retention rates over the intervention; and changing trends in and between outcome measures.

*Qualitative data*

Interview transcripts were analysed thematically using Framework analysis.[14,15] Framework Analysis is a manual, matrix method which facilitates thematic and cross-case interpretation. Interviews at each of the three time points addressed specific feasibility aims. All qualitative data were analysed together following study completion.

***Recruitment and Sample***

Patient screening and recruitment were conducted by clinical teams at both sites. Eligible patients were provided with a Patient Information Pack. Participants provided written consent via the LifeGuide website. For this feasibility study we sought to recruit 60 AS patients (30 per site). For a feasibility study of this nature, 60 participants was judged sufficient to allow us to answer the aims of the study.

**Results**

As a feasibility study, our outcomes were feasibility driven rather than hypothesis driven. Findings are presented according to the specific aims of the feasibility study:

- recruitment processes and resources
- intervention management and procedures
- suitability of outcome measures.

***Recruitment Processes and Resources***

Recruitment took place between December 2015 and October 2016. 128 patients were screened for inclusion in the study (89 UHS, 39 UCLH). 48 were excluded as they did not fulfil inclusion criteria. 13 patients agreed and consented to take part in the study (6 UHS, 7 UCLH), representing an overall response rate of 16%. Of these, 10 were randomised to receive the PROACTIVE intervention and 3 TAU (see figure 1). Participant demographics can be seen in table 1.

Thirty patients who declined to participate indicated their reasons for non-participation when they returned their decline slip, 12 were working and could not get time off to participate, 8 said they were too busy, 6 saw no need in participating as they were happy with their AS management, and 4 were carers for family members.

All participants completed baseline assessments, 10 (77%) completed post-intervention questionnaires (7 intervention, 3 TAU), and 3 (23%) completed 6 month follow up questionnaires (2 intervention, 1 TAU).

***Anxiety and living with AS***: With regards to qualitative interviews, 12 participants completed their pre-intervention interview (9 intervention, 3 TAU); 9 completed post-intervention interviews (6 intervention, 3 TAU); and 9 completed 6 month follow-up interviews (7 intervention, 2 TAU).

When asked during interviews about anxiety related to their prostate cancer all participants indicated they experienced increased levels of anxiety during the period whilst undergoing medical procedures leading to their cancer diagnosis. However, when receiving their diagnosis, almost all were reassured by their treating consultant that their prostate cancer was not severe and unlikely to cause them problems in the future. In the majority of cases participants did not perceive their cancer as impacting on their day-to-day life, and felt little cause for anxiety. Typically, the only time participants indicated they experienced any anxiety due to their cancer was when they were undergoing periodic assessments to monitor the progress of their condition (see quotations 1 and 2 in Table 2).

***Motivation for taking part and perceived ineligibility for the intervention***: Participants' primary motivation for taking part in the study was a desire to 'give something back.' Few participants were motivated by a desire for personal benefit. Indeed, due to participants' perception of their cancer as non-severe, some felt their inclusion was unwarranted, with some referring to feeling like a 'fraud' or 'imposter' as they didn't feel their condition justified intervention (see quotation 3 in Table 2).

***Views on randomisation***: No participants expressed concerns relating to the randomisation process. Only one of the three participants allocated to TAU expressed disappointment at not receiving the PROACTIVE intervention.

***Intervention Management and Procedures***

No issues were identified relating to the feasibility and acceptability of the trial procedures. Those allocated to the PROACTIVE intervention experienced no difficulties attending workshops, and only one participant failed to attend all their workshop sessions. Participants were happy with the group format of the workshops, and felt comfortable discussing their experiences within the group.

The size of the groups (containing 4 to 6 participants) was considered optimal, allowing participants an adequate opportunity to speak about their own experiences. Participants felt the number of workshops conducted, as well as the length of each workshop, was acceptable. Almost all participants were complimentary of the quality of the group sessions.

Facilitators leading the sessions at both study sites were perceived as 'skilful' and 'knowledgeable.' The sessions themselves being perceived as 'informal and informative', with subject matter well explained by facilitators. The level of detail included in the sessions was also perceived as 'just right', being neither too complex nor too simple.

***Group workshops***: Participants were encouraged during workshops to set lifestyle goals to improve their health and limit anxiety. However, qualitative interviews revealed many participants did not set any personal goals. Some said that they 'don't like setting goals', while others did not see adjustments to their lifestyle as necessary due to AS not causing anxiety and/or being unlikely to impact on the development of their cancer.

No participant had utilised the taught breathing techniques for anxiety related to their cancer, as none felt their condition had raised their anxiety levels sufficiently to warrant utilisation. However, some participants had used the breathing exercises for non-cancer related reasons and found them beneficial, and others felt they would utilise the breathing techniques should circumstances warrant in the future (see quotation 4 in Table 2).

***Online modules***: Adherence to the online PROACTIVE modules was lower than for workshops, with a number of participants indicating during interviews that they did not access the web resource at all. Those who had accessed the website tended to do so only during the period of attending workshops to read around the topics covered during the workshops.

The main reason for not accessing the website was that participants perceived their condition as not severe, with some indicating they would access the resource if their cancer progressed. Other factors affecting adherence to the website included a lack of available time and low usage of the internet generally.

Although a number of participants had not utilised the website, it was considered an acceptable intervention. It was typically viewed by participants as an adjunct to the workshops, the latter perceived as the essential component of the PROACTIVE intervention. Those who did access the website indicated no problems navigating the website, with language and content perceived to be at an appropriate level (see quotation 5 in Table 2).

***Perceptions of the impact of the intervention***: Some participants made lifestyle changes such as increased exercise or reduced alcohol consumption following the PROACTIVE intervention. However, participants were almost universally in agreement that involvement with the PROACTIVE intervention had not led to any significant changes to their day-to-day life or anxiety levels. Participants did however, perceive they derived benefit from the PROACTIVE intervention. In particular participants valued being able to share experiences with other prostate cancer patients 'in the same boat' as themselves. Participants typically felt reassured by listening and talking with other prostate cancer patients on AS.

A number of participants also received contradictory advice and recommendations during their NHS care, and were additionally found to value the opportunity to receive accurate definitive information from an expert in prostate cancer care. Participants often described feeling better informed around prostate cancer and AS as a result of receiving the PROACTIVE intervention. This led to participants feeling more secure in their decision to choose AS as a treatment option, and reassured about their continued future on AS (see quotations 6 and 7 in Table 2).

***Suitability of Outcome Measures***

All participants described the completion of study questionnaires as acceptable. Participants also indicated none of the questionnaires contained items deemed intrusive or sensitive in nature. However, some participants indicated they felt some questions were irrelevant to them, and would only relate to patients with a more severe illness (see quotation 8 in Table 2).

Despite participants qualitatively reporting a lack of anxiety, HADS scores at baseline indicate clinical levels of anxiety in all participants, and clinical levels of depression in 8 (61.5%) participants. All outcome measure scores remained largely stable for participants post-intervention (see table 3) and at 6 month follow-up (see table 4).

**Discussion**

Although most aspects of the research design and PROACTIVE intervention were acceptable to those participating in the study, three major problems were identified:

- recruitment of sufficient numbers
- low utilisation of internet modules
- self-perceived low levels of anxiety

The study identified 80 eligible participants, but just 13 patients (16%) agreed to participate. Although the majority of those declining to participate cited work/time constraints for non-participation, interviews with participants indicated they did not consider themselves to be suffering from undue anxiety related to their cancer diagnosis and AS monitoring. The present study found lower levels of self perceived anxiety than previously published research.[6] It is noteworthy that many participants in the present study indicated that they had felt reassured by their treating consultant that their cancer was not severe and unlikely to cause them problems in the future. It is possible that greater confidence in AS as a treatment strategy by consultants has had a positive impact on prostate cancer patients' levels of anxiety. However, further research is required to explore this further.

Qualitative data indicated participants felt the PROACTIVE intervention had not impacted on their perceived anxiety levels, and quantitative data also indicated no trends towards any clinically meaningful differences between those treated with TAU and PROACTIVE. Interestingly, whilst quantitative data suggested all participants were experiencing clinically significant levels of anxiety, qualitative data revealed participants did not feel they were experiencing raised anxiety. Previous research has found problems in accurately screening cancer patients for clinical anxiety using the HADS anxiety subscale.[16] Given the conflicting levels of prevalence of anxiety detected amongst prostate cancer patients managed on AS (previous studies found levels ranging from 13% to 45%)[6] it is recommended further research be conducted to accurately assess levels of anxiety amongst AS prostate cancer patients longitudinally, and explore reasons for discrepancies between screening scales and patients' perceived experience.

One of the aims of the PROACTIVE intervention was to support AS patients with a better understanding of the processes involved in AS and why it represents the preferred treatment approach. Participants indicated during qualitative interviews they felt better informed about prostate cancer and AS as a result of receiving the PROACTIVE intervention, with many indicating they felt more secure in their decision to choose AS as a treatment option. Many participants also valued the peer support in the group workshop, a finding congruent with the findings of a recent qualitative synthesis of studies exploring prostate cancer patients' experiences of supportive care provision.[17]

To conclude, although participants were found to value the opportunity to share and discuss experiences with other prostate cancer patients on AS, and receive detailed authoritive information on AS, the study encountered significant issues with recruitment, utilisation of online modules, and participant anxiety levels. Although it is not advisable to conduct further research into PROACTIVE in its current format, further research is required to explore more thoroughly the impact of AS on anxiety amongst men with localized prostate cancer.

**Acknowledgements**
We would like to offer our thanks to the clinical care teams at the participating sites, as well as to the individual participants for taking part in the study. We would also like to thank Neophytos Petrides for their input into the study. This study was conceived by Professor George Lewith in collaboration with the study team. Sadly George died suddenly during the course of the investigation, and we would like to dedicate this paper to him.

**Source of funding**
This project was funded by Prostate Cancer UK, grant reference number PG14-023. Early development of the research design was funded by the Prostate Cancer Support Organisation. The views expressed here are those solely of the authors.

**Conflicts of interest**
Professor Richardson is a National Institute for Health Research (NIHR) Senior Investigator. The views expressed in this article are those of the author(s) and not necessarily those of the NHS, the NIHR, or the Department of Health. The authors declare that they have no conflicts of interests.

**References**
1. Wilt TJ, Brawer MK, Jones KM, et al. Radical prostatectomy versus observation for localized prostate cancer. *N Engl J Med.* 2012;367:203-13.
2. National Institute for Health and Clinical Excellence. Prostate Cancer: Diagnosis and Treatment (CG175). 2014. Cited 2018 March 01. Available from: http://www.nice.org.uk/guidance/CG175.
3. Mohler J, Bahnson RR, Boston B, et al. NCCN clinical practice guidelines in oncology: prostate cancer. *J Natl Compr Canc Netw.* 2010;8:162-200.
4. Heidenreich A, Bastian PJ, Bellmunt J, et al. European Association of Urology. EAU guidelines on prostate cancer. part 1: screening, diagnosis, and local treatment with curative intent-update 2013. *Eur Urol.* 2014;65:124-37.
5. Carter HB, Albertsen PC, Barry MJ, et al. Early detection of prostate cancer: AUA Guideline. *J Urol.* 2013;190:419-26.
6. Ruane-McAteer E, Porter S, O'Sullivan JM, Santin O,Prue G. Active surveillance for favorable-risk prostate cancer: Is there a greater psychological impact than previously thought? A systematic, mixed studies literature review. *Psycho-Oncology.* 2017;26:1411-1421.
7. Watts S. The assessment and management of anxiety and depression in prostate cancer patients being managed with active surveillance. 2014, PhD Thesis: University of Southampton.
8. Latini DM, Hart SL, Knight SJ, et al. The relationship between anxiety and time to treatment for patients with prostate cancer on surveillance. *J Urol.* 2007;178:826-31.
9. Patel MI, DeConcini DT, Lopez-Corona E, Ohori M, Wheeler T, Scardino PT. An analysis of men with clinically localized prostate cancer who deferred definitive therapy. *J Urol.* 2004;171:1520-1524.
10. Yardley L, Morrison L, Bradbury K, Muller I. The person-based approach to intervention development: application to digital health-related behavior change interventions. *J Med Internet Res.* 2015;17:e30.

11. Zigmond AS, Snaith RP. The hospital anxiety and depression scale. *Acta Psychiatr Scand.* 1983;67:361-370.
12. Stewart-Brown SL, Platt S, Tennant A, et al. The Warwick-Edinburgh Mental Well-being Scale (WEMWBS): a valid and reliable tool for measuring mental well-being in diverse populations and projects. *J Epidemiol Community Health.* 2011;65:A38-A39.
13. Roth AJ, Rosenfeld B, Kornblith AB, et al. The memorial anxiety scale for prostate cancer: validation of a new scale to measure anxiety in men with with prostate cancer. *Cancer.* 2003;97:2910-8.
14. Ritchie J, Lewis J. Qualitative Research Practice. 2003, London: Sage.
15. Patton MQ. Qualitative Research and Evaluation Methods. 2002, Thousand Oaks, CA: Sage.
16. Vodermaier A, Millman RD. Accuracy of the Hospital Anxiety and Depression Scale as a screening tool in cancer patients: a systematic review and meta-analysis. *Support Care Cancer.* 2011;19:1899-1908.
17. King AJL, Evans M, Moore THM, et al. Prostate cancer and supportive care: a systematic review and qualitative synthesis of men's experiences and unmet needs. *Eur J Cancer Care.* 2015;24:618-634.

**Table 1: Participant demographics**

| | TAU (n=3) | Intervention (n=10) | Total (n=13) |
|---|---|---|---|

| | | | |
|---|---|---|---|
| Age (years/mean) | 66.67<br>(SD=2.89)<br>(range 65-70) | 66.30<br>(SD=8.37)<br>(range 52-76) | 66.38<br>(SD=7.34)<br>(range 52-76) |
| Education | | | |
| - Secondary | 0 (0%) | 1 (10%) | 1 (7.7%) |
| - College | 3 (100%) | 3 (30%) | 6 (46.2%) |
| - Higher Education | 0 (0%) | 6 (6%) | 6 (46.2%) |
| Employment | | | |
| - Retired | 3 (100%) | 7 (70%) | 10 (76.9%) |
| - Full Time | 0 (0%) | 2 (20%) | 2 (15.4%) |
| - Part Time | 0 (0%) | 1 (10%) | 1 (7.7%) |
| Ethnicity | | | |
| - White British | 3 (100%) | 8 (80%) | 11 (84.6%) |
| - Black African | 0 (0%) | 1 (10%) | 1 (7.7%) |
| - Black Caribbean | 0 (0%) | 1 (10%) | 1 (7.7%) |
| Marriage Status | | | |
| - Married | 1 (33.3%) | 8 (80%) | 9 (69.2%) |
| - Cohabiting | 1 (33.3%) | 0 (0%) | 1 (7.7%) |
| - Divorced | 1 (33.3%) | 2 (20%) | 3 (23.1%) |
| Time since diagnosis (months/mean) | 2.33<br>(SD=2.31)<br>(range 1-5) | 4.10<br>(SD=3.51)<br>(range 1-11) | 3.69<br>(SD=3.28)<br>(range 1-11) |

**Table 2: Examples of participant quotes from qualitative interviews** (participants identified by ACT (from proACTive) followed by participant number)

***Anxiety and living with AS***

*1. 'Well he[consultant] was very reassuring and fairly dismissive of it, so we didn't think too much about it… he'd said that he hadn't been able to find anything more serious, so basically he said – well it's good news, you're clear, apart from this little thing which isn't going to be a problem.'* [ACT121 pre-intervention interview]

**Table 3: Within group comparison: scores at baseline and post intervention**

| Outcome measure | Mean at baseline | Mean at follow-up | Difference (95% CI) |
|---|---|---|---|
| TAU | | | |

| | | | |
|---|---|---|---|
| HADS Anxiety | 12.67 (SD=0.58) | 14.67 (SD=0.58) | 2.00 (-0.48, 4.48) |
| HADS Depression | 7.67 (SD=0.58) | 7.67 (SD=1.15) | 0.00 (-2.48, 2.48) |
| HADS Total | 20.33 (SD=0.58) | 22.33 (SD=1.53) | 2.00 (-2.30, 6.30) |
| MAX-PC | 17.67 (SD=3.06) | 13.67 (SD=4.04) | -4.00 (-10.57, 2.57) |
| WEMWBS | 60.00 (SD=6.25) | 58.33 (SD=4.73) | -1.67 (-20.50, 17.14) |
| Intervention | | | |
| HADS Anxiety | 13.22 (SD=1.99) | 13.29 (SD=1.50) | 0.14 (-0.85, 1.13) |
| HADS Depression | 8.67 (SD=1.73) | 8.86 (SD=1.34) | 0.14 (-0.65, 1.13) |
| HADS Total | 21.89 (SD=2.03) | 22.14 (SD=1.57) | 0.29 (-0.74, 1.32) |
| MAX-PC | 17.44 (SD=6.69) | 18.43 (SD=5.26) | 1.86 (-1.58, 5.29) |
| WEMWBS | 55.67 (SD=11.96) | 57.00 (SD=11.31) | 2.00 (-0.07, 4.07) |

**Table 4: Outcome measure scores at 6 month follow-up**

| Outcome measure | TAU | Intervention (mean/SD) |
|---|---|---|
| HADS Anxiety | 13 | 13.5 (0.71) |
| HADS Depression | 9 | 9 (1.41) |
| HADS Total | 22 | 22.50 (0.71) |
| MAX-PC | 19 | 17 (1.41) |
| WEMWBS | 61 | 53.00 ( 15.56) |