

# Improving wellbeing of prostate cancer survivors using the NADA acupuncture protocol: a clinical outcome study<sup>1</sup>

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## Abstract

**Background:** Prostate cancer survivors experience a range of troublesome symptoms related to cancer and its treatments.

**Objective:** To evaluate the feasibility of using the National Acupuncture Detoxification Association (NADA) 5-point ear acupuncture protocol to improve wellbeing of men diagnosed with prostate cancer.

**Design:** A single-arm observational clinical outcome study using before and after measurements.

**Setting:** Located in a National Health Service cancer treatment centre in southern England.

**Patients:** Men diagnosed with prostate cancer,  $\geq 35$  years old, without relapse or metastatic disease,  $\geq 6$  months post-active cancer treatment, experiencing symptoms and/or side effects of cancer or its treatments.

**Intervention:** 20 patients completed 8 weekly NADA treatments in small groups of up to 5.

**Main Outcome Measures:** Changes in scores at end of treatment (EOT) over Baseline for: patient reported outcomes (Measure Yourself Medical Outcomes Profile (MYMOP)), health status (Short Form 36 (SF-36)), and interference of symptoms on daily life (Symptom Related Daily Interference Scale (SRDIS)). Acceptability of NADA treatment was assessed using semi-structured questionnaires.

**Results:** Mean MYMOP profile change score showed 1.69 points improvement on a 7-point scale ( $sd=1.25$ ,  $p<.000$ ,  $n=19$ ). SF-36 results showed improvements in Vitality and Physical Composite Summary Scores. Significant reductions in the interference of symptoms on daily life were recorded for work, social, sleep, mood, concentration and quality of life. No serious adverse effects were reported. Overall, men found NADA treatment in small groups acceptable.

### Conclusions:

NADA ear acupuncture may offer a simple non-pharmacological method of supporting prostate cancer survivors in managing troublesome symptoms. Further research is warranted.

## Key Words

Acupuncture

Auriculotherapy

Cancer survivorship

Ear acupuncture

National Acupuncture Detoxification Association (NADA)

NADA protocol

Prostate cancer  
Quality of life  
Wellbeing

## Introduction

Prostate cancer is the second most common cancer worldwide for males, and the fourth most common cancer overall, with more than 1.11 million new cases diagnosed in 2012.<sup>1</sup> Treatment options include surgery, external beam or internal (brachytherapy) radiotherapy, hormonal therapies, chemotherapy and watchful waiting.<sup>2</sup> Survival is improving, and currently more than 84% of men diagnosed with prostate cancer in the United Kingdom (UK) survive the disease by at least 10 years.<sup>3</sup>

In spite of improved diagnosis, treatment, and survival rates, there is considerable physical and psychosocial morbidity associated with prostate cancer. In addition to general worries about a cancer diagnosis, there are significant side effects of treatments and medications used, including hormonal therapies, steroids, and pain medications. Distressing side effects of hormonal therapies alone include hot flashes, osteoporosis, anemia, fatigue, sarcopenia, gynecomastia, loss of libido, erectile dysfunction, and increased risk of diabetes, cardiovascular disease, and cardiac events. Emotional side effects of diagnosis and treatment include distress, anxiety, irritability and depression.<sup>4</sup>

Patients rarely present with one symptom, and cancer survivors have been reported to experience as many as 13 concurrent symptoms.<sup>5-6</sup> Cancer survivorship programmes focus on the complex health issues faced by survivors, who may experience side effects of cancer and its treatment (both short and long-term) and late consequences of treatment.<sup>7-8</sup> These may occur alongside pre-existing comorbidities, as well as health issues that arise as a consequence of aging (more than a third of prostate cancers are diagnosed in men aged over 75 years).<sup>3</sup>

The evidence for using acupuncture in the supportive care of cancer survivors is increasing, for a range of physical and psychosocial issues.<sup>9-10</sup> Its application in prostate cancer has focused mainly on hormone treatment-related hot flashes.<sup>9,11</sup> Some of these studies have investigated wider symptomology including hot flash related distress,<sup>12</sup> sleep quality and overall vitality,<sup>13</sup> and quality of life<sup>13-15</sup>. However, to our knowledge there is no acupuncture research that investigates the wider health issues experienced by prostate cancer survivors.

In our previous acupuncture research, we measured health issues beyond a single symptom. This included assessing the physical and emotional wellbeing of early breast cancer survivors experiencing hormonal-treatment-related hot flashes and night sweats,<sup>16-17</sup> and the wellbeing and quality of life of cancer survivors with upper body lymphoedema.<sup>18-19</sup> Our aim is to integrate acupuncture into the National Health Service (NHS) as a treatment option that encompasses the complex consequences of cancer and its treatments. To achieve this, it is necessary to explore modes of acupuncture that meet the constraints of the NHS. We are interested in approaches that are simple to deliver, require minimal training, and can accommodate potentially large numbers of patients for potentially long periods of time (in

the UK, the lifetime risk of developing prostate cancer is 1 in 8; survivors may experience long term consequences for many years following active treatment<sup>3</sup>). Resources are a key consideration. As more cancer patients survive for increasingly long periods following diagnosis, the burden of healthcare is increasing, and inexpensive forms of supportive care are essential.

## Rationale

We are building on our ten years of experience of using the five-point ear acupuncture protocol developed by the National Acupuncture Detoxification Association (NADA).<sup>20</sup> This standardised treatment requires no diagnosis, and can be administered in the UK by healthcare professionals who are non-acupuncturists after a brief period of training, as well as by fully qualified acupuncturists. Delivery in a group setting facilitates the treatment of up to 20 patients by one therapist in an hour and a half.<sup>21</sup>

Developed initially as an adjunct to conventional therapy in substance misuse detoxification, there is an increasing body of evidence for using the NADA protocol to address a range of health related issues, including behavioural health and cancer care.<sup>20</sup> In cancer care, it is used to manage hot flashes experienced by female and male cancer survivors. In our previous study, we reported promising results of using NADA treatment to manage breast cancer treatment-related hot flashes and night sweats, and demonstrated improved emotional and physical wellbeing.<sup>16, 22</sup> Harding et al investigated using the NADA protocol to manage hot flashes experienced by prostate cancer survivors, demonstrating significant reductions in hot flash severity, as well as reductions in cancer related concerns and improvement in wellbeing using the Measure Yourself Concerns and Well-being (MYCAW) questionnaire.<sup>15</sup>

A legacy provided the opportunity to expand our acupuncture provision, and we wished to offer treatment to men as well as women. In doing this, we wanted to measure the effects of treatment, in order to obtain data to support development of further service provision and to assess the potential for future research. We chose to do this in the form of a clinical outcome study, which adopts a systematic approach whilst permitting normal treatment, and assesses safety and benefit to patients, the key starting point for most clinical research.<sup>23</sup>

As in our previous NADA research, we aimed to measure systematically the effects in both the short and longer-terms, to obtain a first measure of this approach, and to test the suitability of the delivery. The main questions were:

1. What symptoms do prostate cancer survivors find troublesome?
2. Can the NADA protocol address these symptoms and improve wellbeing?
3. Is NADA treatment in a group setting acceptable to prostate cancer survivors?

This paper reports quantitative data; qualitative data gathered from focus groups and semi-structured questionnaires will be reported separately. In reporting the study, this paper adheres to the Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) 2010.<sup>24</sup>

## Methods

### Participants

The study was open to men diagnosed with prostate cancer, who were under the care of an oncology consultant at Mount Vernon Cancer Centre. Patients were referred by their oncology consultant, members of the nursing team, or could self-refer via the cancer information and drop-in centre.

Eligibility criteria included: men aged 35 years or more diagnosed with prostate cancer; without relapse or metastatic disease; six or more months post active cancer treatment (surgery, chemotherapy, radiotherapy); if applicable, taking adjuvant hormonal treatment for six or more months; experiencing symptoms and/or side effects of cancer or cancer treatments; able to speak, read and understand English; and able to complete a course of eight NADA treatments in a maximum of ten weeks. Men with advanced disease were excluded.

The NADA specialist (TD) screened referrals by telephone, and sent eligible men a package including a participant information sheet explaining the service, baseline medical and sociodemographic questionnaires, and an invitation to attend an intake interview. At this interview, the NADA specialist answered any questions, and then obtained written consent. She also took a case history, in order to gain insight into the patient's symptoms and overall well-being. This focused on health since diagnosis, sleep, bowel and urinary habits, hot flashes and sweats, cancer treatment-related sexual concerns, somatic symptoms (such as headaches, general aches and pains), energy levels, emotional state and any other issues the survivor wished to discuss. The NADA specialist then administered the baseline outcome measures and booked future appointments. During this session, the NADA specialist also gave a sample treatment, administering the NADA five points in one ear, to familiarise survivors with the experience.

### Acupuncture

All participants received weekly acupuncture treatment for eight sessions using the NADA protocol. This comprises the auricular points Auricular Sympathetic, Shen Men, Kidney and Liver on both ears, with Upper Lung on the right ear, and Lower Lung on the left (see Figures 1 and 2). Needles were inserted bilaterally into the five acupuncture points and retained for 40 minutes. Single use, sterile, stainless steel needles 0.20mm diameter and 7mm long with plastic handles, manufactured by D&D, and packaged for detox protocols (10 needles per pack) were used. The NADA specialist inserted needles perpendicular to the skin with a swift single-handed motion rotating 180° clockwise to ensure smooth insertion, until the needle tip was supported in the cartilage (about 1 to 2 mm). No stimulation was applied.

*<Insert deValois.Figure1>*

Figure 1. The NADA protocol, right ear (Photo courtesy of NADA UK)

*<Insert deValois. Figure2>*

Figure 2. The NADA protocol, left ear (Photo courtesy of NADA UK)

Clinics took place on Thursday mornings, with up to five participants per clinic (the number that comfortably accommodated in the centre's largest clinical space). Each participant

spent a few minutes with the NADA specialist in private, to discuss any issues. She then escorted them to the adjacent room, where they sat with other patients to have the needles inserted in situ in the group setting. The NADA specialist prefaced the needling with a brief relaxation session, during which she directed their focus to their breathing and to becoming comfortable. (This practice developed in response to patient feedback; discomfort when sitting was a widespread issue in the groups, due to the cancer site.) The men then sat together for 40 minutes, until the needles were removed in situ.

Typically in detox settings, patients are enrolled in a supportive multi-component programme, of which NADA is one option.<sup>20, 25-26</sup> The prostate cancer survivors had no structured supportive programme (although one quarter of them attended the hospital-based monthly prostate cancer support group) and we felt it was important for them to have time to discuss any concerns, or their experience of acupuncture, privately with the NADA specialist.

This arrangement also allowed the NADA specialist to recommend lifestyle changes, where appropriate. This was tailored to the individual's specific needs, and could include advice on dietary habits (usually regarding eating breakfast and regular meals), exercise, rest, managing stress and the practical management of hot flashes, or referral to other services, such as counselling and relaxation classes. The NADA specialist aimed to keep one-to-one contact time to a minimum, seeing patients individually for about five minutes. She applied this flexibly according to the needs of the individual.

After the eighth and final treatment, the NADA specialist administered the final questionnaires, including an Exit Questionnaire (see Figure 3). She also reviewed the patient's progress through treatment, and recorded their comments on their experience of acupuncture treatment. The 4-week and 18-week follow-up questionnaires were posted to the patient at the appropriate time.

The NADA specialist was a holistic therapist who had completed NADA UK detoxification training in the year prior to this project.

## Design

This was an evaluation to assess the feasibility of offering a regular NADA service, as well as to assess the potential for further research. To monitor this, we used before and after measurements. Survivors attended for eight NADA treatments, with treatments once a week. They were monitored at the following measurement points: before treatment commenced (Baseline), at the end of treatment (EOT), four weeks after EOT (Post tx 4) and 18 weeks after EOT (Post tx 18) (see Figure 3).

<Insert deValois.Figure3>

Figure 3: Flow diagram showing the outcome measurement points.

As is standard practice in our centre for all patients attending for complementary therapies, the survivors gave written consent to be treated and to complete questionnaires. This project took place at the Lynda Jackson Macmillan Centre, a cancer drop-in and information centre associated with Mount Vernon Cancer Centre in Northwood, Middlesex, England. These patients were treated from May 2013 through July 2014.

## Outcome measures

We selected three questionnaires as outcome measures:

- 1) The Measure Your Medical Outcome Profile (MYMOP) is a validated questionnaire used widely to evaluate interventions based on holistic and participative principles, and allows patients to specify and measure outcomes that are important to them.<sup>27-29</sup> We chose MYMOP as an appropriate measure to collect data on the most troublesome symptoms and facilitate measurement of changes in wellbeing (our main questions 1 and 2).

With structured guidance, the respondent specifies one mandatory symptom (Symptom 1) and an optional second symptom (Symptom 2) for which they are seeking treatment. He may optionally specify one activity of daily living that is affected by the symptom(s). These, in addition to his feeling of wellbeing, are rated on a seven-point scale (6 is “as bad as it could be; 0 is “as good as it could be”), according to the severity over the past week. On the MYMOP follow-up questionnaires, the respondent rates his original concerns. The “MYMOP profile score” is the mean of all the individual scored items.

- 2) The Short Form 36 Health Survey (SF-36) is a validated generic 36-item functional status questionnaire that assesses eight domains of physical and psychological health.<sup>30</sup> Responses are calculated on a scale (0 is “worst possible health state”; 100 is “best possible health state”). Self-administered, it can be completed in ten minutes, is used widely in studies of oncology and complementary medicine, and is a National Cancer Survivorship Initiative (NCSI) standard measure for outcomes relevant to cancer survivorship<sup>7</sup>. We chose the SF-36 to measure improvements in wellbeing (our main question 2), and to allow the possibility of comparison with other studies, including our own previous research.
- 3) Symptom Related Daily Interference Scale (SRDIS) was a modification of the validated Hot Flash Daily Interference Scale (HFDIS), used to assess the impact of hot flashes in daily activities and overall quality of life.<sup>31</sup> Although validated for menopausal hot flashes, it has been used in prostate cancer studies.<sup>13</sup> With the originator’s permission, we modified the questions to encompass symptoms beyond hot flashes. Thus, we changed the instructions to describe how much “*hot flashes* have interfered with each aspect of your life” to how much “*your symptoms* have interfered...”. We also changed the word “housework” to “household tasks” in Item 1: “Work (work outside the home and housework)”. As advised by Dr Carpenter, we changed the name of this measure to “*Symptom Related Daily Interference Scale*” to avoid confusion with the HFDIS. Although this altered format has not been validated, we felt it would provide an adequate first measure of the effect of NADA on the interference of symptoms on daily life (question 2).

Frequency of measurement is illustrated in Figure 3. Three other semi-structured questionnaires, designed to elicit written feedback from participants about their experience of having acupuncture and participating in the study, were administered at EOT, and at four and 18 weeks after EOT (Post tx 4 and Post tx 18).



## Sample size and statistical methodology

As this was a clinical outcomes study, we had no existing data from the outcome measures to calculate an effect size and hence estimate a sample size. However, we could recruit a sample of 20 patients in a reasonable time in our centre. This facilitated testing feasibility of recruitment, retention, questionnaire completion, as well as the acceptability of group clinics. It also allowed us to determine the key symptoms patients were experiencing. A post hoc analysis for an effect size of 1.4 (MYMOP Profile: mean change = 1.69, SD = 1.25) with 19 patients and alpha = 0.05 suggests the study had a power of 0.99.

Data were analysed across all participants using SPSS version 22. Frequency counts were calculated for sociodemographic and clinical variables. Paired *t* tests or Wilcoxon signed rank tests (for non-parametric data) were used for comparing MYMOP, SF-36 and SRDIS baseline data with responses at EOT.

We calculated MYMOP and SRDIS changes by taking the EOT scores and subtracting them from the baseline scores. A positive change score then denotes improvement. For consistency, with SF-36 the reverse was applied and the baseline score was subtracted from the EOT score for each scale so that again a positive change denotes improvement.

For SF36 scale scores, if the participants had responded to at least half of the items in a scale the mean response to completed items was imputed to replace missing values.<sup>30</sup> The two summary scale scores – Physical Component Summary (PCS) and Mental Component Summary (MCS) - were calculated according to the SF36 Scoring Manual<sup>32</sup> using UK normal population data.<sup>33</sup>

## Results

### Recruitment, compliance and questionnaire return

Twenty men consented to treatment, of whom 19 completed eight NADA treatments. One man withdrew from the study after four treatments, as chronic bowel problems made it difficult for him to sit for the required period. Questionnaire completion and return was high, with all 19 men returning all questionnaires. Data were missing for some items on the SF-36; these were missing at random.

### Patient characteristics

Table 1 displays the demographic and clinical data for the 20 men collected at baseline. The mean age at baseline was 68 years (SD=6.6, range 59 – 79). The mean time since prostate cancer diagnosis was 3.7 years (SD=2.6, range 1.0 – 10.75).

*<Insert ACU.2014.deValois.Table1>*

Patients self-reported up to four concurrent non-cancer related co-morbidities (see Figure 4). We analysed these using the International Classification of Primary Care (ICPC) categories (see Table 2).<sup>34</sup> Self-reported use of medication was also recorded, and showed patients were taking up to seven pharmaceutical preparations, including over the counter products such as aspirin (see Figure 4). Only two reported taking vitamins and minerals as dietary supplements.

<Insert deValois.Figure4>

Figure 4: Frequency of self-reported non-cancer related co-morbidities and use of medications

<Insert ACU.2014.deValois.Table2>

Table 2: Self-reported non-cancer related co-morbidities by ICPC category

### **MYMOP results**

Table 3 shows the MYMOP scores at Baseline and EOT, and the changes in scores.

<Insert ACU.2014.deValois.Table3>

### **Analysis of troublesome symptoms**

To gain insight into what the men found most troublesome, we analysed the symptoms on the MYMOPs. All patients specified symptoms for both Symptom 1 and Symptom 2 (Symptom 1 is mandatory; Symptom 2 is optional) for a total of 40 symptoms. We categorised these using the ICPC classifications (see Figure 5). As the ICPC categorise hot flashes as Female Genital, we have listed these separately as Hot Flashes. More specific symptoms within these categories include loss of sexual appetite (Male Genital), lack of urinary control (Urological), sleep problems, feeling low, memory (Psychological), dizziness (Neurological), appetite, bowel control (Digestive), and tiredness, fatigue and pain (General & Unspecified). Activities that the men found troublesome to perform related mostly to physical activities linked to work and leisure (n=17). Bowel incontinence limited the activities of one man; another reported diminished sexual activity; and one recorded that his symptoms prevented him going to work.

<Insert deValois.Figure5>

Figure 5: Analysis of MYMOP symptoms (categorised by ICPC)

### **SF-36 and SRDIS**

Table 4 shows the SF-36 scores, and the SRDIS results are presented in Table 5.

<Insert ACU.2014.deValois.Table4>

<Insert ACU.2014.deValois.Table5>

### **Acceptability to patients**

The three semi-structured questionnaires asked patients to comment on their perception of having acupuncture, and were used to monitor perceived short- and long-term benefits. The Exit Questionnaire, used at the end of the eighth treatment, asked "Have you found these sessions beneficial". Eighteen respondents replied "Yes"; one replied "the jury is still out". The Post tx 4 and Post tx 18 Questionnaires asked "How worthwhile do you think your ear acupuncture has been?", and the responses are shown in Figure 6.

<Insert deValois.Figure6>

Figure 6: Responses to "How worthwhile do you think your ear acupuncture has been?"

At Post tx 18, 17 respondents said they were pleased they took part in the sessions, and 18 said they would recommend ear acupuncture to a friend.

### Adverse events

Generally, NADA acupuncture was well tolerated, with no serious adverse effects reported or observed. There was occasional bleeding at the needle site. These results accord with our previous experience of using the NADA protocol, as well as with another study using the NADA protocol.<sup>15-16</sup>

### Discussion

Our aim in this clinical outcomes study was to gather data to inform decision-making about service provision and future research. Our assessment provides preliminary data about 1) the symptoms prostate cancer survivors find troublesome; 2) whether the NADA protocol can address these symptoms; and 3) whether this treatment is acceptable to prostate cancer survivors.

We wished to progress the discussion about symptoms beyond hot flashes, which had been the main focus of acupuncture studies for prostate cancer related conditions. Our aim is to begin to address the complex, multiple symptoms that are experienced by cancer survivors.<sup>6-8</sup> A recent analysis of the symptom burden experienced by oncology patients reported that the top five symptoms reported by prostate cancer survivors at follow-up were fatigue, disturbed sleep, distress, pain, and dry mouth.<sup>35</sup>

In answer to our first question, MYMOP demonstrates that prostate cancer survivors are troubled by symptoms other than, or in addition to, hot flushes. Urinary problems were the second most frequently reported symptoms in our clinic, followed by musculoskeletal, and tiredness/fatigue. The high number of men presenting with hot flashes may have been in part due to our initial presentations to the hospital's prostate cancer support group, which focussed on discussions about hot flashes. Furthermore, healthcare professionals in our cancer centre were familiar with our existing NADA service for breast cancer-treatment related hot flushes, and may have assumed this service had the same single focus. Using the data we have gathered from this study, we can communicate more clearly with patients and healthcare professionals about the wider benefits of treatment.

In answer to our second question, MYMOP results demonstrated that the NADA protocol could address the variety of symptoms experienced by this patient group, and all MYMOP domains were statistically and clinically significant at the end of eight treatments. That symptoms were less troublesome was further substantiated by the SRDIS outcomes, showing significant reductions in symptom interference in six of the ten domains. This was a modification of a questionnaire validated for use with menopausal women; in future work, we will identify outcome measures validated for use with men with prostate cancer.<sup>36</sup>

SF-36 results showed significant improvement in Vitality and the Physical Component Summary only. It has been suggested that the SF-36 is not sensitive to small treatment effects;<sup>27</sup> however, its widespread use and global assessment for healthcare, and its particular application in cancer survivorship, make it useful for comparing study populations.

The men found NADA treatment in small groups acceptable, as evidenced by the 95% (n=19) completion rate of eight NADA sessions. This was substantiated further by their overall positive response that they were glad they took part in the sessions and would recommend ear acupuncture to a friend. The benefits of treatment appear to have diminished as time from EOT increased. In future work, we would plan to apply the selected outcome measures at post-treatment measurement points, to gather further data on long-term effects of treatment.

No serious adverse effects were reported or observed, and bleeding at the needle site was the only minor adverse effect reported by the NADA specialist. This accords with findings of major safety studies on acupuncture generally,<sup>37-38</sup> as well as with the findings from our existing body of work with the NADA protocol.

To our knowledge, this is the first work to explore the use of acupuncture, and specifically the NADA protocol, to address the wider range of symptoms that prostate cancer survivors find troublesome. This moves towards recognising and addressing the complex presentations of multiple, concurrent symptoms experienced by cancer survivors, and this is beginning to be explored in work identifying symptom clusters. While research in this area is hampered by lack of an agreed, clinically relevant definition of “symptom clusters”, there is increasing recognition that multiple symptoms affect prognosis, quality of life, and functional status. Awareness of this is important for patient management.<sup>5-6,39</sup>

Our clinical data suggests that using the NADA protocol can affect a wide range of symptoms, and we have previously reported improvements in physical and emotional health for breast cancer patients receiving the NADA treatment to manage hot flashes. Carter et al<sup>25</sup> and Peckham and Mangold<sup>40</sup> have published articles reporting symptom-related outcomes relating to substance use disorders. That the NADA protocol can have a wide-ranging effect may be due to its action of promoting homeostasis to improve an individual’s endocrine and autonomic function,<sup>41</sup> thus leading to improvements in overall wellbeing.

## **Conclusions**

In the short term, decision makers in our centre can use the data we have gathered to inform their decisions about provision and further development of an NADA ear acupuncture service for prostate cancer survivors. We are also assessing the data to plan and design a formal research study, as we believe that further research is warranted.

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## **Disclosure Statement**

No competing financial interest exists for any of the authors.

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**TABLE 1 Demographic and clinical characteristics at Baseline**

<i>Demographic characteristics</i>	<i>n = 20 (%)</i>
<b>Marital status</b>	
Single (never married)	1 (5)
Married (first marriage)	15 (75)
Re-married	2 (10)
Living with partner	1 (5)
Separated	1 (5)
<b>Educational qualifications</b>	
Less than compulsory school education	2 (10)
Compulsory school education (e.g. school certificate, GCSEs)	10 (50)
Post compulsory school education below university level	2 (10)
University level	4 (20)
Postgraduate level	1 (5)
Missing	1 (5)
<b>Current employment status</b>	
Retired	12 (60)
Not working at present	2 (10)
Working part time	1 (5)
Working full time	5 (25)
<b>Ethnic background</b>	
Black African	1 (5)
Indian	1 (5)
Iraqi	1 (5)
White British	15 (75)
White other	2 (10)
<b>Clinical characteristics</b>	
<b>Cancer treatment history</b>	
Surgery	4 (20)
External beam radiotherapy	11 (55)
Brachytherapy	4 (20)
Hormonal therapies (current)	16 (80)
10 Zoladex, 5 Prostav, 1 Bicalutamide	
Hormonal therapies (previous)	4 (20)
3 Zoladex, 1 Prostav	
Watch and wait	11 (55)
<b>Time taking hormonal therapies</b>	
0 (i.e. not currently on hormones)	4 (20)
6 – 12 months	5 (25)
1 – 2 years	5 (25)
2 – 4 years	1 (5)
> 4 years	2 (10)
Missing	3 (15)
<b>Participants with previous experience of acupuncture</b>	
Yes (for non-cancer related problems)	8 (40)
No	12 (60)

\* Abbreviations: GCSEs, general certificate of secondary education.



**TABLE 2 Non-cancer related co-morbidities by ICPC Classification**

ICPC Classification	Frequency
General and unspecified	2
Digestive	2
Cardiovascular	6
Musculoskeletal	8
Neurological	1
Psychological	2
Respiratory	4
Endocrine/metabolic and nutritional	2
Urological	3
Lymphedema	1
Total	31

**TABLE 3 MYMOP outcomes**

	Baseline	EOT		$\Delta$ Baseline – EOT		
	Mean (SD)	Mean (SD)	Mean (SD)	t	df	p
n = 29						
Symptom 1	4.84 (1.07)	2.68 (1.83)	<i>2.16 (1.83)</i>	5.13	18	<b>0.000</b>
Symptom 2	4.26 (1.33)	2.53 (1.54)	<i>1.74 (1.20)</i>	6.34	18	<b>0.000</b>
Activity	3.89 (1.78)	2.50 (1.79)	<i>1.39 (1.65)</i>	3.57	17	<b>0.002</b>
Wellbeing	2.84 (1.71)	1.58 (1.31)	<i>1.26 (1.88)</i>	2.92	18	<b>0.009</b>
MYMOP Profile	3.99 (1.05)	2.29 (1.33)	<i>1.69 (1.25)</i>	5.89	18	<b>0.000</b>

\* Domains scored 0 (“as good as it could be”) to 6 (“as bad as it could be”). Lower scores indicate better health.

†p = significance on a 2-tailed paired *t* test

‡**Bold** indicates statistical significance (p<0.05).

§*Italics* indicate clinical significance (change  $\geq$  0.5 point)

**TABLE 4 SF-36 outcomes**

<i>n</i> = 17	Baseline	EOT	Δ EOT – Baseline			
Scale	Mean (SD)	Mean (SD)	Mean (SD)	<i>t</i>	df	<i>p</i>
<b>PF</b>	69.92 (24.32)	72.02 (25.59)	-3.11 (18.16)	0.71	16	0.491
<b>RP</b>	56.62 (32.06)	63.97 (28.38)	-7.35 (17.98)	1.69	16	0.111
<b>BP</b>	57.12 (25.92)	62.71 (27.49)	-5.59 (20.22)	1.14	16	0.271
<b>GH</b>	59.33 (20.81)	61.33 (17.24)	-2.00 (15.39)	0.50	14	0.623
<b>VT</b>	48.05 (18.92)	57.42 (21.06)	-9.38 (13.5)	2.78	15	<b>0.014</b>
<b>SF</b>	70.59 (31.23)	69.12 (30.97)	1.47 (24.16)	-0.25	116	0.805
<b>RE</b>	77.94 (29.01)	75.49 (25.60)	2.45 (24.07)	-0.42	16	0.680
<b>MH</b>	73.44 (21.74)	71.25 (20.37)	2.19 (17.60)	-0.50	15	0.626
<b>PCS</b>	35.13 (11.82)	38.62 (12.33)	3.48 (6.95)	-0.21	16	<b>0.055</b>
<b>MCS</b>	50.29 (11.05)	50.21 (9.92)	-0.09 (10.07)	0.04	16	0.971

\* PF = Physical Functioning; RP = Role limitation due to Physical problem; BP = Bodily Pain; GH = General Health; VT = Vitality; SF = Social Functioning; RE = Role limitation due to Emotional problem; MH = Mental Health; PCS = Physical Component Summary; MCS = Mental Component Summary  
† Domains scored 0 (“worst possible health state”) to 100 (“best possible health state”). Higher scores indicate better quality of life.  
‡ *p* = significance on a 2 tailed paired *t* test.  
§ **Bold** indicates statistical significance (*p*<0.05)

**TABLE 5 SRDIS outcomes**

<i>n</i> = 17	Baseline	EOT	Δ Baseline – EOT			
Scale	Mean (SD)	Mean (SD)	Mean (SD)	<i>t</i>	df	<i>p</i>
<b>Work</b>	4.68(3.83)	2.89 (2.45)	-1.77 (2.44)	3.20	18	<b>0.005</b>
<b>Social</b>	3.58 (3.34)	1.84 (2.01)	-1.74 (2.42)	3.12	18	<b>0.006</b>
<b>Leisure</b>	3.63 (3.53)	2.53 (2.89)	-1.11 (3.05)	1.58	18	0.132
<b>Sleep</b>	5.47 (3.22)	3.79 (2.68)	-1.68 (3.28)	2.24	18	<b>0.038</b>
<b>Mood</b>	4.68 (3.20)	2.58 (2.59)	-2.11 (3.07)	3.00	18	<b>0.008</b>
<b>Concentration</b>	3.47 (3.13)	2.32 (2.19)	-1.16 (2.48)	2.04	18	<b>0.057</b>
<b>Relaxation</b>	3.18 (3.03)	2.47 (2.29)	-0.71 (2.85)	1.02	16	0.322
<b>Sexuality</b>	7.11 (4.32)	6.05 (3.89)	-1.05 (2.70)	1.70	18	0.106
<b>Enjoyment</b>	3.68 (3.53)	2.89 (2.81)	-0.79 (2.39)	1.44	18	0.168
<b>Quality of life</b>	4.32 (3.47)	3.11 (2.69)	-1.21 (2.37)	2.23	18	<b>0.039</b>

\* Domains scored 0 (“does not interfere”) to 10 (“completely interfere”). Lower scores indicate better health.  
† *p* = significance on a 2-tailed paired *t* test  
‡ **Bold** indicates statistical significance (*p*<0.05).

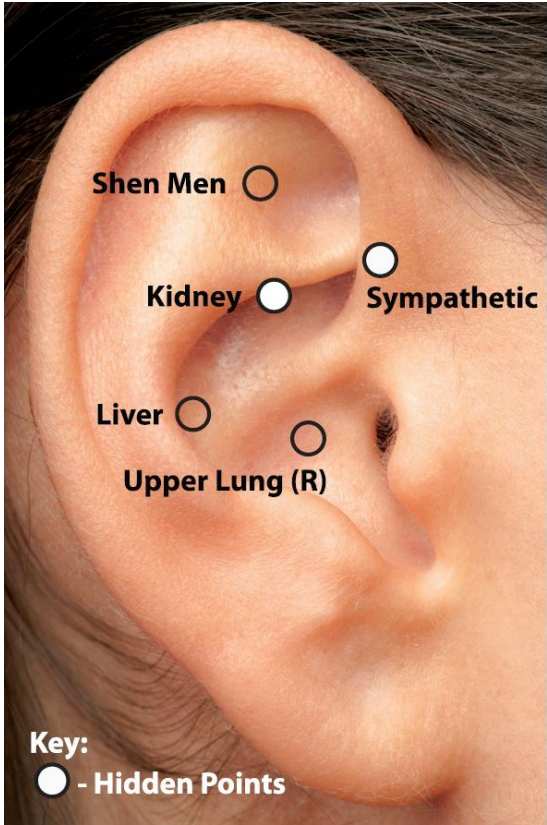


Figure 1. The NADA protocol, right ear (Photo courtesy of NADA UK)

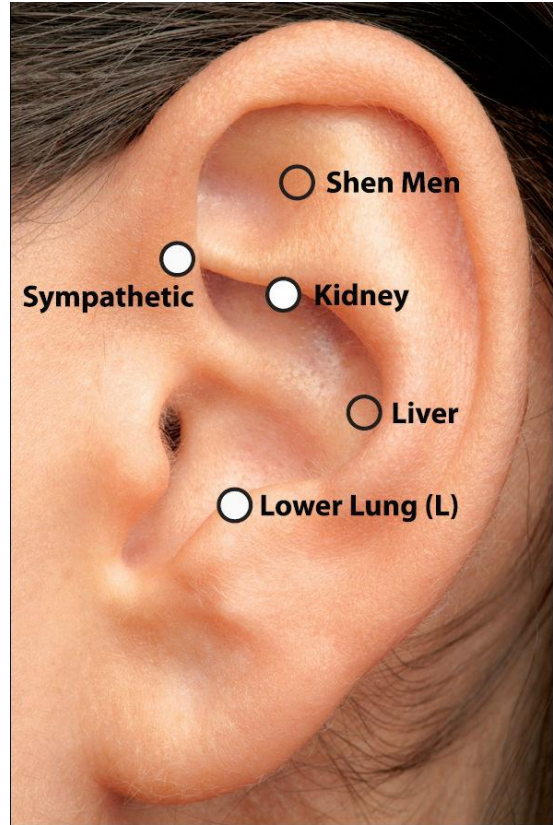
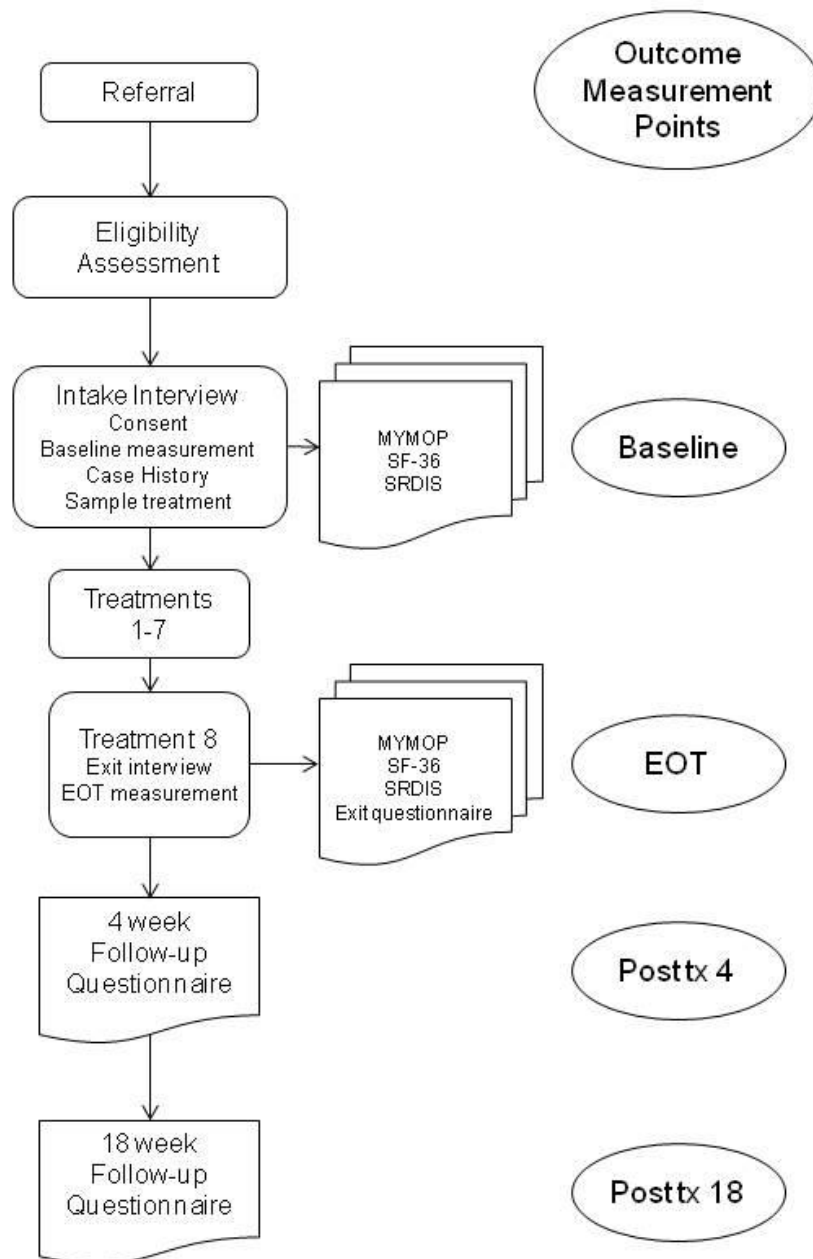


Figure 2. The NADA protocol, left ear (Photo courtesy of NADA UK)

**Figure 3: Flow diagram showing the outcome measurement points**



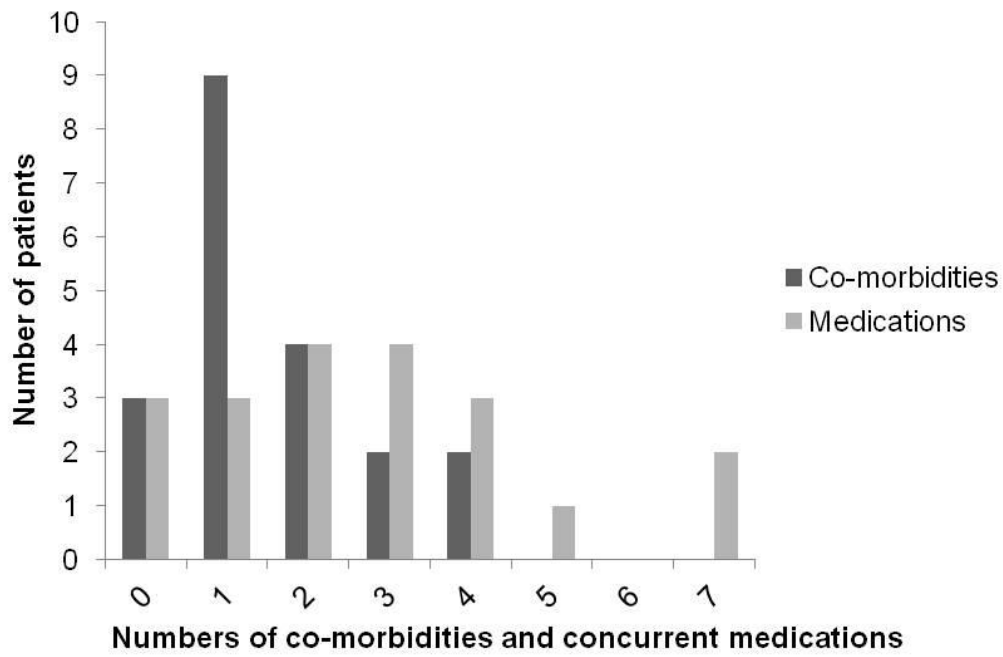


Figure 4: Frequency of self-reported non-cancer related co-morbidities and use of medications

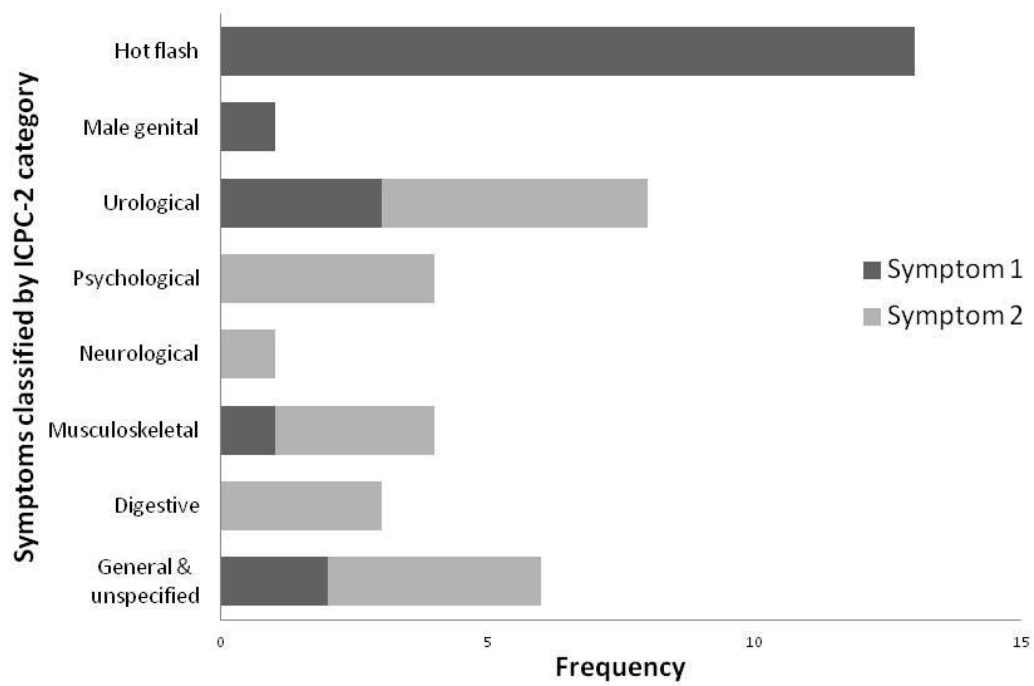


Figure 5: Analysis of MYMOP symptoms (categorised by ICPC)

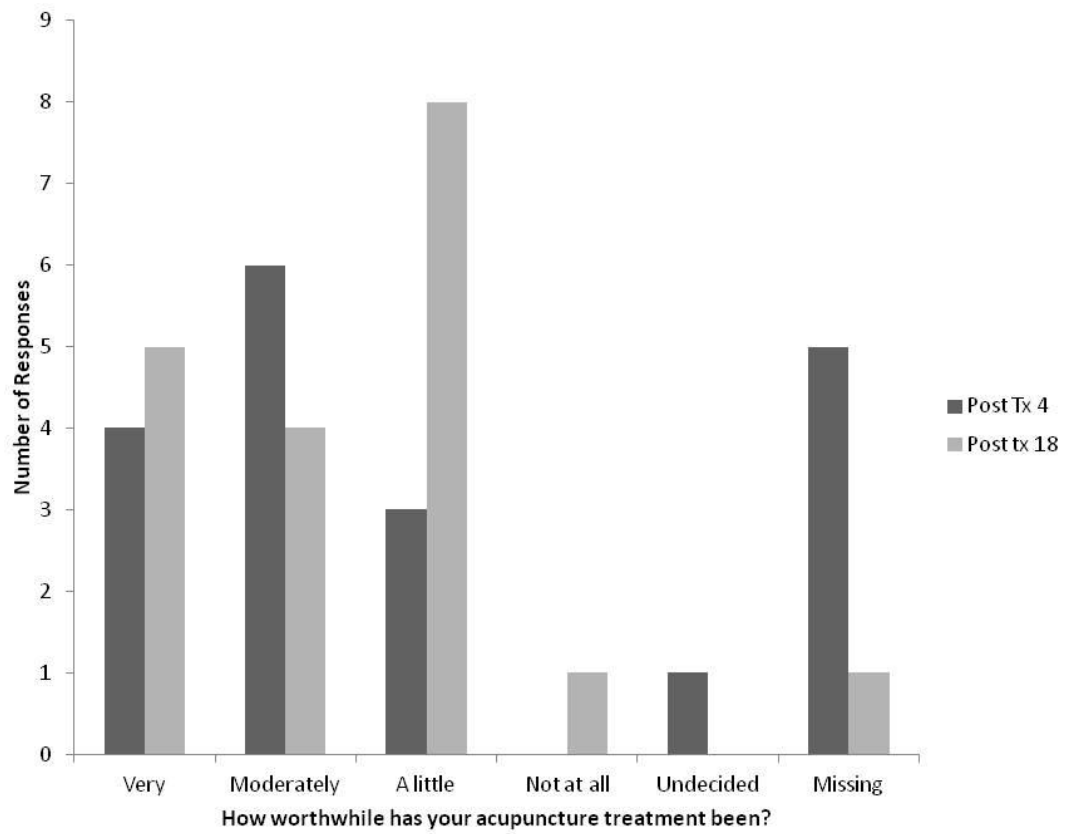


Figure 6: Responses to “How worthwhile do you think your ear acupuncture has been?”