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Decisional Conflict is Associated with Treatment Modality and not Disease Knowledge in South African Men with Prostate Cancer: Baseline Results from a Longitudinal Prospective Observational Study

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Abstract

Background: Decisional conflict (DC) is a psychological construct that an individual experiences in making a decision that involves risk, loss, regret, or challenges to one's values. This study assessed DC in a cohort of South African men undergoing curative treatment for localised prostate cancer (LPC). The objectives were to (1) to examine the association between DC and prostate cancer knowledge (PCK), demographics, state anxiety, prostate cancer anxiety and time to treatment and (2) to compare levels of DC between treatment groups [prostatectomy (RP) and external beam radiation (RT)].

Method: Data, comprising the Decisional Conflict Scale (DCS), Prostate Cancer Knowledge (PCK), State-Trait Anxiety Inventory (STAI-S), the Memorial Anxiety Scale for Prostate Cancer (MAX-PC) and demographic data from 83 participants of a larger prospective longitudinal observational study examining depression, anxiety and health related quality of life (DAHCaP) were analysed.

Results: The mean age of participants was 63 years (RP 61yrs and RT 65yrs; $p< 0.001$). Most were of mixed ancestry (72.3%). The total DCS scores between the treatment groups (RP 25.00 and RT 18.75; $p = 0.037$) and two DCS sub-scores-uncertainty ($p = 0.033$), and support ($p = 0.048$), were significantly higher in the RP group. A statistically significant negative correlation was observed between state anxiety and time between diagnosis and treatment in the RP group (Spearman's rho = −0.368; $p = 0.030$). There was no correlation between the DCS score and PCK within each treatment group (Spearman's rho RP = −0.249 and RT = −0.001).

Conclusion: Decisional conflict was higher in men undergoing RP. Men were more anxious in the RP group regarding the time treatment was received from diagnosis. No correlation was observed between DC and PCK. Pre-surgical management of DC should include shared decision making (SDM) which is cognisant of patients' values facilitated by a customised decision aid.

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Keywords
decisional conflict, radical prostatectomy, radiation treatment, prostate cancer knowledge, state trait anxiety inventory, memorial anxiety scale for prostate cancer

Introduction

In simple terms, decisional conflict (DC) reflects the level of comfort an individual faces in making a decision.[1] Complex treatment decisions are an inherent part of uro-oncology and are associated with high levels of uncertainty that have the potential to cause DC.[2] DC is a psychological construct that an individual experiences in making a decision that involves risk, loss, regret or challenges to one's values[3] Lack of information about treatment alternatives and their consequences, deficiencies in decision making, emotional distress and pressure from others have been implicated in increased DC.[4]

Choosing a treatment for localised prostate cancer (LPC) can create uncertainty and conflict as the current evidence on the efficacy and survival rates following curative treatments for LPC are comparable. Radical prostatectomy as well as radiation therapy (RT), whether given as external beam therapy, brachytherapy or in combination, are both recommended treatment options for low, intermediate and high-risk LPC.[5] This is supported by an extensive review of men being treated for LPC over a 10-year period, which demonstrated equivalence regardless of the treatment modality chosen.[6] Gains in life expectancy are accompanied by the risk of long-term and troublesome side effects. Urinary incontinence and erectile dysfunction (ED) are long-term side effects commonly seen with RP.[5] However, in those treated with external beam radiation, secondary malignancies, ED and gastrointestinal complications may be experienced.[7]

Outcomes, in studies examining the association between PCK and DC, vary. Kaplan., *et al* found in economically disadvantaged men with prostate cancer, poor knowledge was associated with increased DC.[8] A pilot study that tested the utility of a decision aid for prostate cancer in African American men without prostate cancer, found that improved knowledge reduced DC.[9] On the other hand, a study by Daum et al,[10] showed that PCK was also associated with decision making difficulty.

The inclination towards one treatment over another for LPC is a matter of personal preference and beliefs. Possible reason cited for choosing RP is for complete removal of the tumour whilst those selecting RT are concerned about the side effects arising from RP and being afraid of surgery[11-13].

A review of psychological issues in prostate cancer suggested that confusion from having to choose between therapeutic options may exacerbate anxiety.[14] For instance Kother et al., showed that emotional distress was common in uro-oncology and could be a predictor of decisional conflict.[15]

Xu et al.,[16] in his qualitative review on men's perspectives in choosing prostate cancer treatment, advanced the involvement of family and friends, particularly those already diagnosed with prostate cancer, as variables that assisted patients in making their treatment choices.

This study aimed to assess DC in a cohort of South African men undergoing curative treatment for LPC. The objectives were (1) to examine the association between DC and prostate cancer knowledge (PCK), demographics, state of general anxiety, prostate cancer anxiety and time to treatment and (2) to compare levels of DC between treatment groups [prostatectomy (RP) and external beam radiation (RT)].

Methods

Study and Sample Procedures

We used the baseline data obtained between June 2019 and November 2021 of 83 men already recruited into an extensive prospective observational study for DAHCaP. The DAHCaP study is evaluating depression, anxiety and health related quality of life in men undergoing treatment Radical Prostectomy (RP), External Beam Radiotherapy (EBRT) and Brachytherapy (BT) for localised prostate cancer (LPC). These parameters are assessed at baseline (once a treatment decision was made and when participants were scheduled to receive treatment) and then 12 weekly for 1 year. Study participants were recruited from 2 academic centres: Tygerberg Hospital (TBH) and Groote Schuur Hospital (GSH) in Cape Town, South Africa, by a doctoral student. Consecutive sampling was employed. A sample size of 83 achieved 99.8% power to detect a correlation coefficient of 0.5 or more at the 0.05 level of significance on the DCS.

Description of setting and study methods

Demographic Data, the Decisional Conflict Scale (DCS), Prostate Cancer Knowledge (PCK) and the Spielberger State-Trait Anxiety (STAI-S) which formed part of scheduled baseline visits for the DAHCaP study were utilised.

Men, histologically diagnosed with low to intermediate risk prostate cancer, who had already decided on their treatment and were scheduled to receive their treatment were invited by the treating clinician to participate in the study. Prior to commencement of the study the protocol was presented to clinicians that would be involved in screening patients for the study. Men with hypogonadism, evidence of metastases or on androgen deprivation therapy (ADT), were excluded from the study. Written informed consent was obtained from participants. The study was approved by the HREC of University of Stellenbosch and HREC of University of Cape Town. Self-

administered questionnaires were handed to participants to complete. Participants that had difficulty in reading the questions were assisted by the researcher. The researcher checked all questionnaires for missing data and where this was identified the participant was requested to complete the appropriate fields. All data was entered by the data capturer onto REDCaP, an electronic database with a secure server. Quality checks for missing data on REDCaP was also done. Participants' study data in print and the electronic system were de-identified using a personal identification number (PIN). Information that could identify participants was stored separately and securely. The reporting of the study conforms to the STROBE guidelines.[17]

All study documents were available in English, Afrikaans and isiXhosa, the main languages in the region. The following baseline assessments which are part of the larger study were used in this analysis.

Measures

Socio Demographic Data. We collected data on age, marital status, educational level, comorbidities, smoking and drinking status.

The Decisional Conflict Scale (DCS). The DCS is comprised of 16 items that are divided into 5 subscales (Appendix 1). Items are rated on a 5-point Likert Scale (0 = strongly agree, 4 = strongly disagree).[18] The total and subscale scores were calculated by averaging the individual item scores and multiplying it by 25, to get a total out of 100. The higher the score the greater the degree of DC.[4]

Prostate Cancer Knowledge (PCK)

The original PCK questionnaire was modified to include only 10 knowledge statements (of 11) about the natural history of LPC and its treatment options that participants indicated were 'true, false or I don't know'. Each correct answer scores 1 point; whilst a 'don't know', response is assigned 0. The total score reflects an individual's knowledge score.[10]

The Spielberger State-Trait Anxiety (STAI-S)

The Spielberger State-Trait Inventory (STAI- S) measures the current state of anxiety and how anxious patients feel 'right now'. The instrument contains 10 items positively worded for the presence of anxiety, for example 'I am tense' with the remaining 10 items negatively framed for the absence of anxiety, for example 'I am relaxed'. The intensity is graded from 1 'not at all' to 4 'very much so'. Reverse scoring was performed for the 'no anxiety' items. Higher scores indicated greater anxiety.[19]

The Memorial Anxiety Scale for Prostate Cancer (MAX-PC)

The MAX-PC (Memorial Anxiety Scale for Prostate Cancer) measures prostate cancer anxiety, the prostate specific antigen (PSA) test, anxiety and fear of recurrence. It consists of 18 items with 4 responses with a score range between 0 and 3. Thus the total scores can range between 0 and a maximum of 54.[20]

Assistance in Choosing Prostate Cancer Treatment

Participants were asked to select one of 5 statements that best reflected who had helped them in deciding their treatment: I made the decision together with (a) my doctor, (b) my wife/partner, (c) my children, (d) my pastor, (e) another person. (f) I made the decision on my own. Multiple options were allowed which was part of the demographic information.

Ethical Considerations

Ethical approval for the study was obtained from the Health Research Ethics Committee (HREC) at Stellenbosch University (S19/09/019) and the HREC of the University of Cape Town (418/2019). In addition, research principles outlined by the Helsinki declaration, SA Good Clinical Practice Guidelines and the South African Research Medical Research Council (SAMRC) Ethical Guidelines for Research were followed.

Statistical Analysis

All scales were linearly transformed to yield scores out of 100. Scores were compared between treatment groups using non-parametric Mann-Whitney tests, and Spearman's Rho correlation coefficients and were computed to assess linear relationships between scores. Finally, categorical variables were compared between treatment groups using Pearson's chi square tests or Fisher's exact tests as appropriate. Differences were considered significant at a p value of <0.05. Statistical analyses were performed with IBM SPSS Statistics Version 27 (IBM Corp. Released 2020. IBM SPSS Statistics for Windows, Version 27.0. Armonk, NY: IBM Corp).

Results

Data of 83 men were analysed; 36 received RP and 47 RT. Table 1 summarises participants' sociodemographic variables by treatment choice. The mean age of participants was 63 yrs, (RT 65 yrs, RP 61yrs; $p = < 0.001$). Most men (72.3%) self-identified as being of mixed ancestry. A quarter (25.3%) attended primary school only, 60.2% had a secondary school education and 14.5% received a tertiary education. Nearly three-quarters (74.7%) were married or in a permanent

Table 1. Demographic Characteristics by treatment choice.

		RP (n = 36) frequency (%)	RT (n = 47) frequency (%)	Total (n = 83) frequency (%)	p-value
Mean age-years (SD) (range)		61 (6) (48–71)	65 (5) (53–73)	63 (6) (48–73)	0.001
*Race	Black	1 (2.8)	10 (21.3)	11 (13.3)	0.068
	Mixed	30 (83.3)	30 (63.8)	60 (72.3)	
	White	5 (13.9)	6 (12.8)	11 (13.3)	
	Indian	0 (0.0)	1 (2.1)	1 (1.2)	
Religiosity	Not religious	1 (2.8)	3 (6.4)	4 (4.8)	0.613
	Moderately religious	20 (55.6)	22 (46.8)	42 (50.6)	
	Very religious	15 (41.7)	22 (46.8)	37 (44.6)	
Education	Primary school	7 (19.4)	14 (29.8)	21 (25.3)	0.121
	High school	22 (61.1)	28 (59.6)	50 (60.2)	
	Tertiary	7 (19.4)	5 (10.6)	12 (14.5)	
Work status	Employed	5 (13.9)	12 (25.5)	17 (20.5)	0.684
	Unemployed	7 (19.4)	6 (12.8)	13 (15.7)	
	Retrenched	2 (5.6)	3 (6.4)	5 (6.0)	
	Retired	3 (8.3)	4 (8.5)	7 (8.4)	
	Casual worker	6 (16.7)	4 (8.5)	10 (12.0)	
	Pensioner	13 (36.1)	18 (38.3)	31 (37.3)	
Marital status	Single (widowed, divorced, separated)	8 (22.2)	13 (27.7)	21 (25.3)	0.182
	Married (in a relationship)	28 (77.8)	34 (72.4)	62 (74.7)	
Ever smoked cigarettes	No	2 (5.6)	13 (27.7)	15 (18.1)	0.009
	Yes	34 (94.4)	34 (72.3)	68 (81.9)	
Ever drank alcohol	No	3 (8.3)	10 (21.3)	13 (15.7)	0.108
	Yes	33 (91.7)	37 (78.7)	70 (84.3)	
**Help with Rx choice	Doctor	17 (47.2)	20 (42.55)	37 (44.58)	0.671
	Children	6 (16)	4 (8.5)	10 (12.04)	0.258
	Wife/Partner	8 (22.2)	4 (8.5)	12 (14.46)	0.078
	Pastor	2 (5.5)	0 (0)	2 (2.41)	0.102
	Self	13 (36.1)	22 (46.8)	35 (42.16)	0.328
	Other	3 (8.3)	0 (0)	3 (3.61)	0.44

*self-identified by each participant, **multiple options allowed.

relationship. A significantly higher proportion of the prostatectomy group reported having had smoked (p = 0.009). When asked who had helped them make the treatment decision, 47.2% (RP), and 42.55% (RT) had made the treatment decision with the help of a doctor, 36.1% (RP) and 46.8% (RT) made the decision on their own and 22.2% (RP) and 8.5% (RT) indicated that their wife or life partner helped make the decision.

The comparison of DC scores between RP and RT treatments for prostate cancer is depicted in Table 2. The median DCS score for the sample was 23.43 (IQR: 4.69 to 29.69). The total median DCS scores by treatment group were (25.00 for RP and 18.75 for RT; p = 0.037). Two of the DC median subscores were also statistically significantly different between the groups: the uncertainty sub-score (RP 25.00 and RT 0.00; p = 0.033), and the support sub-score (RP 25.00 and RT 16.67; p = 0.048). The informed sub-score was marginally non-significantly different between the groups (RP 29.17 and RT 25.00; p = 0.056).

The median PCK score for the sample was 4.00 (IQR: 2.00 to 6.00). The PCK median score was 4 for both treatment groups and not statistically significantly different. We found no correlation between DCS and PCK (Spearman's rho = RP -0.249 and RT -0.001).

The median STAI-S score for the sample was 30.00 (IQR: 24.5 to 41.50) and for the MAX-PC 8.00 (IQR: 3.00 to 18.00). The median scores for STAI-S (RP 31.00 and RT 30.00) and MAX-PC (RP 12.00 and RT 7.00) per treatment group were similar and non-significantly different. No significant correlation was observed between DCS and STAI-S (Spearman's rho = RP- 0.153 and RT 0.109) or DCS and MAX-PC (Spearman's rho = RP 0.066 and RT 0.020).

No significant difference was observed in medians between time when treatment was received and diagnosis of LPC (RP 214 days and RT 125 days). However, there was a significant negative correlation between STAI-S and time to treatment in the RP group (Spearman's rho = -0.368; p = 0.030).

There was no difference in DCS score between the treatment groups by the person who helped them make the treatment decision (Table 2) (p = 0.085; p = 0.214; p = 0.762; p = 0.302), respectively, for doctor, partner, children, self.

Higher levels of decisional conflict were seen in participants in the RP group that had a primary school education only (RP 29.69 and RT 21.09 p = 0.046).

Table 2. Comparison of scores between treatment choices.

	Prostatectomy (n = 36) median (25th, 75th Percentile)	Radiation therapy (n = 47) median (25th, 75th Percentile)	p-value*
DCS total score	25.00 (12.50, 31.25)	18.75 (1.56, 28.13)	0.037
DCS uncertainty	25.00 (4.17, 25.00)	0.00 (0.00, 25.00)	0.033
DCS informed	29.17 (16.67, 50.00)	25.00 (8.33, 33.33)	0.056
DCS value clarity	25.00 (12.50, 41.67)	25.00 (0.00,41,67)	0.156
DCS support	25.00 (4.17, 25.00)	16.67 (0.00, 25.00)	0.048
DCS effective decision	25.00 (0.00, 25.00)	0.00 (0.00, 25.00)	0.153
PCK-total score	4 (2, 7)	4 (2, 6)	0.803
STAI-S	31.00 (25.00, 41.00)	30.00 (23.00, 43.00)	0.814
MAX-PC	12.00 (4.00, 24.00)	7.00 (3.00, 13.00)	0.147
DSC total score if **Rx choice-Dr	23.44 (14.06, 29.69)	9.38 (0.78, 24.22)	0.085
DSC total score if Rx choice—partner	24.22 (16.41, 32.81)	11.72 (0.00, 24.22)	0.214
DSC total score if Rx choice—children	16.41 (7.81, 29.69)	22.66 (13.28, 26.56)	0.762
DSC total score if Rx choice—self	25.00 (6.25, 37.50)	18.75 (4.69, 29.60)	0.302
DCS total score if education—primary school	29.69 (23.44, 37.50)	21.09 (1.56, 25.00)	0.046
DSC total score if education—secondary school	25.00 (10.94, 31.25)	13.28 (0.78, 28.91)	0.084
DSC total score if education—tertiary	18.75 (0.00, 25.00)	23.44 (7.81, 23.44)	0.755
Time from diagnosis to Rx (days)	214.00 (154.00, 297.00)	125.00 (106.00, 279.00)	0.284

*Mann-Whitney U**Rx choice = Who helped you decide on the treatment for prostate cancer (Doctor, Partner, Children, Self).

Discussion

No significant differences were seen in demographic or disease variables between treatment groups except for the age of participants RP (61yrs) and RT (65 yrs) and more men reported having smoked in the RP (94.4%) and RT (72.3%). There was no correlation between DC and the demographic variables. A study of approximately 500 hundred men with LPC measured the differences in DC between clinical study sites in the US supported a similar view suggesting that the level of DC varied between institutional settings and could not be explained by demographic variables.[21]

We found no correlation between DC total scores, its sub-scores and PCK. These findings are consistent with an analysis of men with LPC participating in a multi-centre clinical trial that reported that those from lower socio-economic areas that did not access health care information outside of the clinic, or seek information independently, may be less aware of the complexities of curative treatments, and therefore experienced less DC.[22] Our results contrast to the US Veterans administration study that showed that newly diagnosed, economically disadvantaged men with LPC with a low level of knowledge on disease had higher levels of DC.[8] Orom et al.,[23] showed that those who were more knowledgeable on prostate cancer had less DC. Although our results differ from those of Kaplan and Orom, it may be argued that demographic variables and data collection tools used could explain some of the differences. Differences in DC outcomes may also be influenced by time (before, during or after a treatment decision is made) or the context in which DC is being measured (care planning, treatment, diagnostic testing etc.)[24,25].

Interestingly, our study showed a statistically significant association between higher total DC scores and the sub-scores of uncertainty and support in the RP treatment group. The informed sub-score was marginally non-significant. A paucity of information exists on the association between DC and curative treatments in LPC. In his investigation Diefenbach et al.,[26] examined decision making strategies in men with LPC and argued that men choosing RP viewed their cancer as being more serious and had greater difficulties in making the decision compared to those receiving RT. A recent discussion on DC described the surgeon-patient interaction as complex and proposed many factors that could cause DC in patients: the nature of the decision, for example the urgency of the procedure, whether it was necessary, and the communication style of the surgeon.[27] Even so an Australian group examining decision-related adjustment in men with LPC treated at outpatient and private clinics, found that men that had decided on a treatment for prostate cancer had less DC compared to those that had not decided on their treatment for LPC[28]

Possible reasons for increased DC in men undergoing RP was outside the ambit of our study. In our opinion, RP patients have a choice between RP and RT and could therefore experience greater levels of uncertainty about a treatment choice conceivably a reason for DC. Conversely those not eligible for surgery have a choice between RT and observation (palliation) and perhaps is associated with lower levels of uncertainty and

DC. As RT is not a commonly understood medical procedure, the communication strategies when preparing patients for treatment might also differ to those undergoing RP.

The median uncertainty sub-scores for RP were higher indicating participants felt more unclear about their choice, unsure about what to choose and that making a treatment decision was not easy. Patients' responses to information are influenced by a range of factors, for example the difficulty and importance of the choices and decisions, the relation to other perceived risks and the relevance of the information for decision making.[29] It may also be likely that a discordance in communication exists about the various treatment plans and how these are communicated to patients by each speciality that could affect the uncertainty sub-scores.[30] Gomella[31] advised that a multidisciplinary team (MDT) should include a urologist, oncologist, radiologist and psychologist to ensure that patients are well informed and satisfied with their choices.

The informed subscale scores were higher in the RP group compared to the RT cohort. Participants in the RP group felt they were less informed about treatment options, their benefits, risks and side effects. Gwede *et al.,* found that almost half of their study participants reported difficulties in making treatment decisions caused by the complex nature of medical information and receiving conflicting or incomplete information from a variety of sources. An inquiry examining the association between information and DC in cancer patients found that inadequate information provision is associated with high DC.[32] A qualitative analysis of treatment preferences in men newly diagnosed with LPC, most of whom had a tertiary education, showed that recall of information was poor, inaccurate or confused even though the urologist had reviewed side effects of each treatment.[33] Niburski et al.,[34] in their scoping review of surgical patients established that SDM decreased DC whilst increasing knowledge improved decisional satisfaction and physician trust.

The support sub-score was higher in the RP group, indicating that they felt that they did not receive enough encouragement, advice or the support for their treatment choice. In keeping with the literature, men who had consulted family and friends (excluding partner/spouse) had greater difficulty in making treatment decisions due to their conflicting opinions in the decision making process.[35]

Bisson et al.,[36] found a low level of psychopathology in men with LPC but suggested that some may develop psychological symptoms. A more recent article on COVID 19 anxiety in men with LPC observed that state anxiety was below clinical levels pre and post treatment (34.7–29.8; P = 0.003).[37] The median STAI-S scores in this study was 30.00. Notably, there was a small but significant correlation between STAI-S and the time between diagnosis and treatment received in the RP group. Possible reasons for choosing RP was for removal of the tumour, the relative time in which surgery could be done and the fear of the cancer spreading that may explain the correlation observed between anxiety and time to treatment in those receiving a prostatectomy[33,38,30,12,14].

We also observed that those in the surgery group with a primary school education only had more DC compared to those in the radiation group. Similarly a Taiwanese study found that men with prostate cancer and a higher than elementary school education had less DC.[39]

Finally, limitations need to be considered. Given the limited sample size and a higher proportion of men of mixed ancestry caution should be exercised when interpreting and generalising the results. Consecutive sampling may also be a factor that should be considered. Measuring DC could well be time sensitive.[24] In our study, DC was not measured at the time the treatment decision was made but when men were scheduled to receive their treatment. Measuring the association of DC at the time a treatment was chosen or post treatment may have demonstrated a different outcome. At the time of protocol development, a validated PCK questionnaire was not

Appendix 1

Subscale with Item Numbers	Description	Items
Informed subscale (items 1,2,3)	Feeling informed about the possible options benefits and risks. Higher score = less informed	I know which treatment options are available to me I know the benefits of each treatment option I know the risks and side effects of each treatment option
Values clarity subscale (items 4,5,6)	Feeling clear about personal values for benefits and risks/side effects	I am clear about which benefit matters most to me I am clear about which risks and side effects matter most to me I am clear about which is more important to me (the benefits or the risks and side effects)
Support subscale (items 7,8,9)	Feeling supported in decision making. Higher score = lack of support	I have enough support from others to make a choice I am choosing without pressure from other I have enough advice to make a choice
Uncertainty subscale (items 10,11,12)	Feeling sure about best possible choice. Higher score = greater uncertainty	I am clear about the best choice for me I feel sure about what to choose this decision is easy for me to make
Effective decision subscale (items 13,14,15,16)	Feeling effective in the decision made	I feel I have made an informed choice my decisions show what is important to me I expect to stick to my decisions I am satisfied with my decisions

available. Many of the published studies have included a greater proportion of Caucasian men with a tertiary education and therefore studies with a diverse demographic such as ours, helps provide a broader perspective in the understanding of decisional conflict in men with LPC.

The evidence from this study suggests that DC may be present in men undergoing RP. Their DC sub-scores indicate that they felt less informed about treatments, side effects and were unclear about their choices. In our view these results may be the basis for stakeholders to consider the use of a customised decision aid to support the SDM process given the limited resources men with LPC attending South African governmental health care institutions have in accessing information on LPC and its treatments on their own. SDM should include patient specific characteristics and values to facilitate a patient centred dialogue.[40] The development of a decision aid that is customised for patient's specific needs, which is easily understandable, educative and one that promotes SDM should be included as part of the management of DC in all patients with LPC.[5]

The present finding might have implications for pursuing a qualitative investigation that may provide a deeper appreciation of the differences in DC observed between treatment groups and reasons for the DC. Validation of the DC scale for an African population should be prioritised. Studies exploring the use of electronic media as sources of information in LPC and its association to DC may also be beneficial.

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Ethical Approval

Ethical approval for the study was obtained from Stellenbosch University (S19/09/019) and the University of Cape Town (418/2019). In addition, research principles outlined by the Helsinki declaration, SA Good Clinical Practice Guidelines and the MRC Ethical Guidelines for Research were followed.

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