Supplementary Information

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Extended sample size and power justification

A Phase II screening randomized trial design was used with a power of 80% and a two-sided type I error rate of 10% for two primary endpoints (anxiety and distress) and two secondary endpoints (adherence and satisfaction). The endpoints were evaluated using graphical sequential procedures to control the family-wise type I error rate at a two-sided alpha of 10% across all primary and secondary endpoints. [1]

As shown in **Figure** S1, if either primary endpoint is significant, the two-sided alpha will be recycled to another primary endpoint. Otherwise, each primary endpoint will be evaluated at a two-sided 5% level. More specifically, the evaluation order of two primary endpoints will be decided according to their p-values. That is, the primary endpoint with the smaller p-value will be first evaluated. If the primary endpoint with the smaller p-value is significant at a two-sided 5% level, the two-sided 5% level will be recycled to the other primary endpoint and the other primary endpoint will be evaluated at a two-sided 10% level. If the primary endpoint with the smaller p-value is not significant at a two-sided 5% level, the other primary endpoint will be evaluated at a two-sided 5% level.

The study will be declared positive if at least one of two primary endpoints is significant. When at least one primary endpoint is positive, the first secondary endpoint (adherence) will be evaluated at a two-sided 5% level (if only one primary endpoint is positive) or at a two-sided 10% level (if both primary endpoints are positive) and, if the first secondary endpoint (adherence) is positive, the second secondary endpoint (satisfaction) will be evaluated at a two-sided alpha recycled from the first secondary endpoint. When both primary endpoints are negative, the secondary objectives will be deemed to be exploratory.

Both primary endpoints will be measured at three time points for each patient and so the sample size was estimated with a linear mixed-effects model through 1,000 simulations (using PASS 2019 [NCSS, LCC. Kaysville, Utah, USA, ncss.com/software/pass] with the procedure 'Mixed Models [Simulation]'). The estimated standard deviation for anxiety was 8.13 points based on the previous prospective single-arm phase II trial [2], and we assumed that the clinically meaningful difference in anxiety between control and

intervention arms is at least 10 points, which yielded an effect size of about 1.2. Thus, the study was designed to detect an effect size of 1.2 for any of primary and secondary endpoints at a two-sided 5% level. In other words, the sample size was estimated to detect an effect size of 1.2 for any primary and secondary endpoints at a two-sided 5% level. For primary and secondary objectives, 38 patients (= 19 patients x two groups) would allow us to have at least 80% power, using a linear mixed-effects model at a two-sided 5% level, when both estimated within- and between-variances are assumed to be one and the autocorrelation is 0.3. With 38 patients, the first secondary objective would have 95% power when a two-sided unpaired t-test is used at a 5% level.

At the time of data analysis, according to Figure S1, the primary endpoint of anxiety was evaluated at a two-sided 5% level and, because the anxiety was significant, another primary endpoint of distress was evaluated at a two-sided 10% level. Since one of the primary endpoints (anxiety) was significant, the study was declared positive. Thus, the first secondary endpoint (adherence) was evaluated at a two-sided 5% level, while the second secondary objective (satisfaction) became exploratory and descriptive because the first secondary endpoint (adherence) was not significant. Consequently, as shown in **Table** 1, the powered analyses were the overall comparisons between groups at all three visits for the two primary endpoints, anxiety and distress, and the first secondary endpoint, patient treatment adherence. All other analyses, such as overall satisfaction, three technical satisfaction questions, comparisons at each visit, pre-interaction outcomes, and subgroup analysis, were exploratory, which should be interpreted descriptively. For those exploratory analyses, no hypothesis testing was performed, so estimated group differences and associated 95% confidence intervals (CIs) were provided without p-values.

References

- 1. Bretz, F., et al., *A graphical approach to sequentially rejective multiple test procedures*. Stat Med, 2009. **28**(4): p. 586-604.
- Atwood, T.F., et al., Establishing a New Clinical Role for Medical Physicists: A Prospective Phase II Trial. Int J Radiat Oncol Biol Phys, 2018. 102(3): p. 635-641.

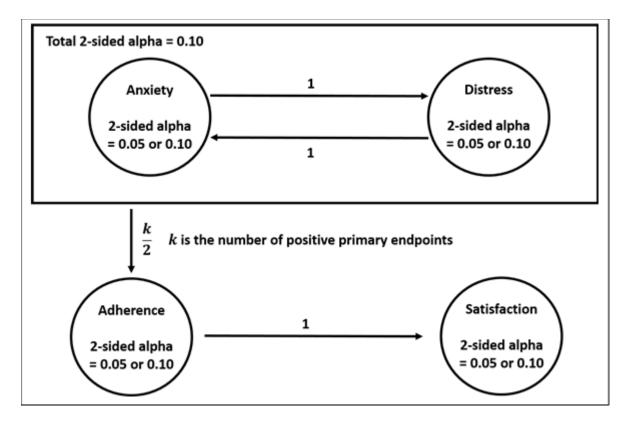


Figure S1. Method of evaluation of the study endpoints. Note *k* is the number of positive primary endpoints. That is, if both anxiety and distress are positive, *k* becomes 2 and so a 2-sided 10% level (i.e., $10\% = 10\% \times 2/2$) will be recycled to adherence; if only one primary endpoint is positive (which is the case of this presented study), *k* becomes 1 and so a 2-sided 5% level (i.e., $5\% = 10\% \times 1/2$) will be recycled to adherence; if both primary endpoints are not positive, *k* becomes 0 and no alpha (i.e., $0\% = 10\% \times 0/2$) will be recycled to adherence and adherence will be deemed to be exploratory.

	All (n=44)	Intervention (n=23)	Control (n=21)	Descriptive p*
Age, year - mean (sd)	56.56 (12.09)	60 (10.63)	52.95	0.056
			(12.71)	
Missing	1	1	0	
Race - no. (%)				>0.99
African-American or Black	32 (73)	16 (70)	16 (76)	
Caucasian or White	9 (20)	5 (22)	4 (19)	
Other race or multiple races	3 (7)	2 (9)	1 (5)	
Hispanic or Latina - no. (%)				>0.99
Yes	2 (5)	1 (4)	1 (5)	
No	41 (93)	21 (91)	20 (95)	
Missing	1 (2)	1 (4)	0 (0)	
Gender - no. (%)				>0.99
Male	1 (2)	1 (4)	0 (0)	
Female	42 (95)	21 (91)	21 (100)	
Other	1 (2)	1 (4)	0 (0)	
Education Level - no. (%)				0.078
Less than high school	6 (14)	5 (22)	1 (5)	
High School/GED	13 (30)	6 (26)	7 (33)	
Some College	8 (18)	4 (17)	4 (19)	
2-year college degree	8 (18)	1 (4)	7 (33)	
4-year college degree	4 (9)	3 (13)	1 (5)	
Graduate/professional degree	5 (11)	4 (17)	1 (5)	
Marital Status - no. (%)				0.841
Married	9 (20)	5 (22)	4 (19)	
Living with partner in a marriage-like relationship	4 (9)	1 (4)	3 (14)	
Widowed	4 (9)	3 (13)	1 (5)	
Divorced	10 (23)	5 (22)	5 (24)	
Separated	3 (7)	2 (9)	1 (5)	
Never married	14 (32)	7 (30)	7 (33)	
Household Income – no. (%)				0.718
Less than 20,000	12 (27)	8 (35)	4 (19)	
20,000-39,999	11 (25)	4 (17)	7 (33)	
40,000-59,999	9 (20)	4 (17)	5 (24)	
60,000-79,999	4 (9)	2 (9)	2 (10)	
80,000-99,999	2 (5)	1 (4)	1 (5)	
100,000-149,000	1 (2)	0 (0)	1 (5)	
150,000 or more	1 (2)	1 (4)	0 (0)	
Missing	4 (9)	3 (13)	1 (5)	
Insurance - no. (%)		· /		0.516
No private insurance	29 (66)	17 (74)	12 (57)	
Private insurance	13 30)	6 (26)	7 (33)	
Missing	2 (5)	0 (0)	2 (10)	
Employment Status - no. (%)	<u> </u>	x-7		0.213
Employed full time	9 (20)	2 (9)	7 (33)	
Employed part time	6 (14)	4 (17)	2 (10)	
Caring for home and/or family	1 (2)	1 (4)	0 (0)	
Unemployed and looking for work	3 (7)	2 (9)	1 (5)	
Unable to work due to illness or disability	10 (23)	4 (17)	6 (29)	
Retired	12 (27)	7 (30)	5 (24)	
Student	3 (7)	3 (13)	0 (0)	

Table S1. Patient baseline characteristics with descriptive p-values

* P value is calculated by t-test for continuous variables and Fisher's exact test for categorical variables; sd, standard deviation

Table S2. Patie	ent pre-interaction	on outcomes
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		Mean (sd)		
	All (n=44)	Intervention (n=23)	Control (n=21)	Difference (95% Cl)
Health Literacy: 3-item, 5-point Likert scale from 1 (none of the time) to 5 (all of the time); e.g., How often do you have problems learning about your medical condition because of difficulty understanding written information?	2.79 (0.59)	2.80 (0.66)	2.78 (0.52)	0.02 (-0.35, 0.39)
Missing	2	1	1	
Perceived Efficacy in Patient-Provider Interactions: 10-item, 5-point Likert scale from 1 (not confident) to 5 (completely confident); e.g., how confident are you in your ability to know what questions to ask a healthcare provider?	4.44 (0.65)	4.23 (0.80)	4.68 (0.28)	-0.45 (-0.82, -0.09)
Patient Activation for Managing Health and Healthcare: 13-item, 5-point Likert scale from 1 (strongly disagree) to 5 (strongly agree); e.g., when all is said and done, I am the person who is responsible for managing my health condition.	4.32 (0.54)	4.28 (0.53)	4.36 (0.55)	-0.08 (-0.41, 0.26)
Anxiety: 6-item, 4-point Likert scale from 1 (not at all) to 4 (very much); e.g., I am tense.	1.95 (0.68)	1.94 (0.80)	1.97 (0.55)	-0.03 (-0.45 <i>,</i> 0.39)
Missing	1	1	0	
Distress: 1-item, 10-point distress thermometer from 1 (no distress) to 10 (extreme distress)	3.66 (2.73)	3.39 (2.76)	3.95 (2.73)	-0.56 (-2.23, 1.11)
Technical Aspects of Care: 3-item, 7-point Likert scale from 1 (not at all) to 7 (very much)				
How satisfied are you with your understanding of the technical aspects of your treatment?	5.53 (1.47)	5.48 (1.47)	5.60 (1.50)	-0.12 (-1.04, 0.80)
Missing	1	0	1	
Do you feel that adequate time has been devoted to explaining the technical aspects of your treatment?	5.67 (1.55)	5.61 (1.62)	5.75 (1.52)	-0.14 (-1.11, 0.82)
Missing	1	0	1	
Do you feel that adequate personnel were				0.05
available to discuss the technical aspects of your	5.98 (1.35)	6.00 (1.21)	5.95 (1.54)	0.05 (-0.81, 0.91)
treatment?				(0.01, 0.91)
Missing	1	0	1	
How satisfied are you with your overall radiation oncology experience? 1-item, 7-point Likert scale from 1 (not at all) to 7 (very much)	5.12 (1.69)	5.17 (1.67)	5.05 (1.76)	0.12 (-0.94 <i>,</i> 1.19)
Missing	1	0	1	

Medical Physics Direct Patient Care Initiative – Communication Intervention Study

- 1) Patient Pre-Interaction Survey
- 2) Patient Post-Interaction Survey

Medical Physics Direct Patient Care Initiative – Communication Intervention Study

Patient Pre-Interaction Survey

With which racial/ethnic group do you most closely identify?

- • African-American or Black
- Caucasian or White
- • Asian
- [©] Native Hawaiian or Other Pacific Islander
- C American Indian or Native Alaskan
- ^O Other race or multiple races (Please specify):

Do you consider yourself Hispanic or Latino?

- • Yes
- • No

With which gender group do you most closely identify?

- ^O Male
- [©] Female
- ^O Trans*
- O Other

When were you born (MM/DD/YYYY)?

What is the highest level of education you have completed?

- C Less than high school
- • High school / GED
- [©] Some college
- [©] 2-year college degree
- [©] 4-year college degree
- Graduate/professional degree

Which of these terms best describes your current marital or personal status?

- ^O Married
- C Living with a partner in a marriage-like relationship
- [©] Widowed
- [©] Divorced
- C Separated
- [©] Never married

What was your household income last year (before taxes)?

- C Less than \$20,000
- [©] \$20,000 \$39,999
- \$40,000 \$59,999
- **°** \$60,000 \$79,999
- \$80,000 \$99,999
- \$100,000 \$149,000
- [©] \$150,000 or more

What kind of health insurance do you currently have? (Select all the choices that apply)

- 🗖 Medicaid
- 🗖 Medicare
- Private insurance (purchased through you or your partner/family member's employer)
- Private insurance (purchased on your own not through an employer)
- I do not have insurance

Which statement best describes your current employment status?

- [©] Employed full time
- [©] Employed part time
- Caring for home and/or family (not employed & looking for paid work)
- ^C Unemployed and looking for work
- ^C Unable to work due to illness or disability
- [©] Retired
- [©] Student

• ^C Other (please explain)

How often do you have someone (like a family member, friend, hospital/clinic worker or caregiver) help you read hospital materials?

- C All of the time
- [©] Most of the time
- [©] Some of the time
- • A little of the time
- • None of the time

How often do you have problems learning about your medical condition because of difficulty understanding written information?

- C All of the time
- ^O Most of the time
- • Some of the time
- • A little of the time
- • None of the time

How confident are you filling out forms by yourself?

- C All of the time
- ^O Most of the time
- ^O Some of the time
- C A little of the time
- • None of the time

The next set of questions concern your feelings about healthcare providers, **in general**. Again, your answers will be kept completely private. Your doctors and nurses will never know how you answered the questions.

How confident are you in your ability to get a healthcare provider to pay attention to what you have to say?

Not	Slightly confident	Somewhat	Moderately	Completely
confident	0	confident	confident	confident

<u> </u>	~	~	~
0	U	O (0

How confident are you in your ability to know what questions to ask a healthcare provider?

Not confident	Slightly confident	Somewhat confident	Moderately confident	Completely confident
0	U	0	0	0

How confident are you in your ability to get a healthcare provider to answer all of your questions?

Not	Slightly confident	Somewhat	Moderately	Completely
confident	Slightly confident	confident	confident	confident
0	0	0	0	0

How confident are you in your ability to ask a healthcare provider questions about your chief health concern?

Not	Slightly confident	Somewhat	Moderately	Completely
confident		confident	confident	confident
0	0	0	0	0

How confident are you in your ability to make the most of your visit with a healthcare provider?

Not	Slightly confident	Somewhat	Moderately	Completely
confident		confident	confident	confident
0	0	0	0	0

How confident are you in your ability to get a healthcare provider to take your chief health concern seriously?

Not	Slightly confident	Somewhat	Moderately	Completely
confident		confident	confident	confident
0	0	0	0	0

How confident are you in your ability to understand what a healthcare provider tells you?

Not confident	Slightly confident	Somewhat confident	Moderately confident	Completely confident
O	0	O	0	0

How confident are you in your ability to get a healthcare provider to do something about your chief health concern?

Not	Slightly confident	Somewhat	Moderately	Completely
confident		confident	confident	confident
0	0	0	0	0

How confident are you in your ability to explain your chief health concern to a healthcare provider?

Not	Slightly confident	Somewhat	Moderately	Completely
confident		confident	confident	confident
0	U	0	0	0

How confident are you in your ability to explain your ability to ask a healthcare provider for more information if you don't understand what he or she said?

Not	Slightly confident	Somewhat	Moderately	Completely
confident		confident	confident	confident
0	U	0	0	0

Please indicate how much you agree or disagree with the following statements: When all is said and done, I am the person who is responsible for managing my health condition.

Strongly disagree	Disagree	Neither agree nor	Agree	Strongly
	Disagree	disagree	Agree	agree
0	\sim	0	V	0

Taking an active role in my own healthcare is the most important factor in determining my health and ability to function.

Strongly disagree	Disagree	Neither agree nor	Agree	Strongly
	O	disagree		agree
<u>v</u>	0	0	0	0

I am confident that I can take actions that will help prevent or minimize some symptoms or problems associated with my health condition.

Strongly disagree	Disagree	Neither agree nor	Λ gree	Strongly
		disagree	Agree	agree
0	0	0	0	0

I know what each of my prescribed medications do.

Strongly disagree	Disagree	Neither agree nor	Agree	Strongly
		disagree		agree
V.	V.	0	∇	0

I am confident that I can tell when I need to do to get my medical care and when I can handle a health problem myself.

Strongly disagree	Disagree	Neither agree nor	Agree	Strongly
		disagree	Agree	agree
0	0	0	<u>v</u>	0

I am confident I can tell my healthcare provider concerns I have even when he or she does not ask.

Strongly disagree	Disagree	Neither agree nor	Agree	Strongly
	O Isugree	disagree	ngice o	agree
0	0	0	0	0

I am confident I can follow through on medical treatments I need to do at home.

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree		
I understand the na	I understand the nature and causes of my health condition(s).					
Strongly disagree	Disagree O	Neither agree nor disagree	Agree	Strongly agree		

I know the different medical treatment options available for my health condition.

Strongly disagree	Disagree	Neither agree nor	Δ gree	Strongly
		disagree	Agice	agree
0	0	0	0	0

I have been able to maintain the lifestyle changes for my health that I have made.

Strongly disagree	Disagree	Neither agree nor disagree	Agree C	Strongly agree	
I know how to pre	I know how to prevent further problems with my health condition.				
Strongly disagree	Disagree	Neither agree nor	Agree	Strongly	
0	0	disagree	0	agree	

I am confident I can figure out solutions when new situations or problems arise with my health condition.

Strongly disagree	Disagree	Neither agree nor	Agree	Strongly
	Disagree	disagree	Agice	agree
0	0	0	\sim	0

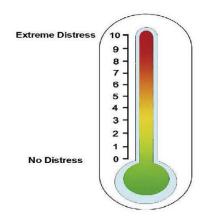
I am confident that I can maintain lifestyle changes like diet and exercise even during times of stress.

Strongly disagree	Disagraa	Neither agree nor	Agree	Strongly
		disagree	Agice	agree
0	0	0	<u>v</u>	0

Below are statements that describe a feeling that may or may not describe how you are feeling **right now**. Read each statement and using the scale shown, select the response that best represents how well that statement describes you.

	Not at all	Somewhat	Moderately	Very Much
Calm	Not at all	• Somewhat	• Moderately	Very Much
Tense	Not at all	© Somewhat	• Moderately	Very Much
Upset	Not at all	• Somewhat	• Moderately	Very Much
Relaxed	Not at all	• Somewhat	• Moderately	Very Much
Content	Not at all	• Somewhat	• Moderately	Very Much
Worried	Not at all	© Somewhat	• Moderately	Very Much

Please look at the picture below. 0 means no distress, and 10 means extreme distress.



Please select the number (0-10) that best describes how much distress you are experiencing right now.

0	1	2	3	4	5	6	7	8	9	10
\mathbf{O}	$^{\circ}$	\mathbf{O}	$^{\circ}$	$^{\circ}$	\mathbf{O}	$^{\circ}$	$^{\circ}$	\mathbf{O}	\mathbf{O}	\mathbf{O}

Finally, we would like to know how you currently feel about the technical aspects of your care. Please rate your feelings on a scale from 1 (Not at all) to 7 (Very Much):

110w satisfic	How satisfied are you with your understanding of the technical aspects of your treatment?												
Not at all	2	3	4	5	6	Very much							
Satisfied	0	0	0	0	0	Satisfied							
Do you feel that adequate time was devoted to explaining the technical aspects of your													
treatment?													
Not at all	2	3	4	5	6	Very much							
Satisfied	0	0	ò	0	Õ	Satisfied							
0	\sim	*	~	~	~	0							
How satisfie	d were you wi	th the availab	ility of staff to	o discuss the te	How satisfied were you with the availability of staff to discuss the technical aspects of your								
two at was a wet?					1	·- · · J · · · ·							
treatment?					Ĩ								
Not at all	2	3	4	5	-	Very much							
	2	3	4	5	6	-							
Not at all	2 ©	3 C	4 O	5 ©	-	Very much							
Not at all Satisfied	2 O od are you with	3 O your radiatio	4 O n oncology ex	5 O perience?	-	Very much							
Not at all Satisfied	2 O and are you with	3 C your radiatio	4 O n oncology ex	5 O aperience?	6 O	Very much							
Not at all Satisfied O How satisfie	2 O are you with 2	3 O your radiatio 3	4 O n oncology ex 4	5 C eperience? 5	-	Very much Satisfied							

Patient Post-Interaction Survey

Thank you for being part of our research study. The purpose of the study is to learn about how we can improve anxiety and distress during radiation therapy treatments. Your answers will be kept completely private. Your doctors and nurses will never know how you answered the questions.

If any questions concern you or are unclear, please feel free to stop and ask the research assistant about them. Also, please remember you do not have to answer any question that you don't want to.

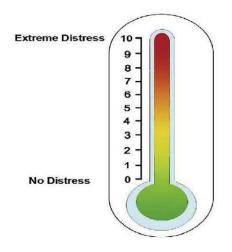
The medical physicist did not fully discuss with me the technical aspects of my treatment.							
Strongly Disagree	Somewhat Disagree	Neither Agree nor Disagree	Somewhat Agree	0	Strongly Agree		
The medical physi	cist showed a genui	ine interest in my he	alth.				
Strongly Disagree	Somewhat Disagree	Neither Agree nor Disagree	Somewhat Agree	0	Strongly Agree		
The medical physi	•	to express concerns	and worries.				
Strongly Disagree	Somewhat Disagree	Neither Agree nor Disagree	Somewhat Agree	0	Strongly Agree		
The medical physi		ompletely at ease du	ring the consultation	on.			
Strongly Disagree	Somewhat Disagree	Neither Agree nor Disagree	Somewhat Agree	0	Strongly Agree		
The medical physi	cist did not treat me	e as an equal in this	consultation.				
Strongly Disagree	Somewhat Disagree	Neither Agree nor Disagree	Somewhat Agree	0	Strongly Agree		
The medical physi		lained everything to	me.				
Strongly Disagree	Somewhat Disagree	Neither Agree nor Disagree	Somewhat Agree	0	Strongly Agree		
The medical physi	cist assured that I u	nderstood my treatn	nent plan.				
Strongly Disagree	Somewhat Disagree	Neither Agree nor Disagree	Somewhat Agree	0	Strongly Agree		
The medical physi	•	native about my trea	atment plan.				
Strongly Disagree	Somewhat Disagree	Neither Agree nor Disagree	Somewhat Agree	0	Strongly Agree		

1.	•	oughts about my tre	atment plan.		
Strongly Disagree	Somewhat Disagree	Neither Agree nor Disagree	Somewhat Agree	0	Strongly Agree
1.	1	and recommendation	ns were clear and ea	sy to	understand.
Strongly Disagree	Somewhat Disagree	Neither Agree nor Disagree	Somewhat Agree	0	Strongly Agree
The medical physi	cist tried to reassure	e and comfort me.			
Strongly Disagree	Somewhat Disagree	Neither Agree nor Disagree	Somewhat Agree	0	Strongly Agree
The medical physi	cist seemed to care	about my feelings.			
Strongly Disagree	Somewhat Disagree	Neither Agree nor Disagree	Somewhat Agree	0	Strongly Agree

Below are statements that describe a feeling that may or may not describe how you are feeling **right now**. Read each statement and using the scale shown, select the response that best represents how well that statement describes you.

	Not at all	Somewhat	Moderately	Very Much
Calm	• Not at all	• Somewhat	• Moderately	O Very Much
Tense	Not at all	• Somewhat	• Moderately	• Very Much
Upset	Not at all	• Somewhat	• Moderately	• Very Much
Relaxed	Not at all	• Somewhat	• Moderately	• Very Much
Content	Not at all	• Somewhat	• Moderately	• Very Much
Worried	Not at all	• Somewhat	• Moderately	• Very Much

Please look at the picture below. 0 means no distress, and 10 means extreme distress.



Please select the number (0-10) that best describes how much distress you have been experiencing in the past week including today.

0	1	2	3	4	5	6	7	8	9	10
\mathbf{O}	\mathbf{O}	\mathbf{O}	\mathbf{O}	\mathbf{O}	$^{\circ}$	$^{\circ}$	$^{\circ}$	\mathbf{O}	\mathbf{O}	\mathbf{O}

care. Please	would like to k rate your feel d are you with	ings on a scale	e from 1 (Not	at all) to 7 (Ve	ery Much):	-
Not at all Satisfied	2 ©	3	4 ©	5 ©	6 ©	Very much Satisfied
Do you feel treatment?	that adequate	time was devo	ted to explain	ing the technic	cal aspects of	your
Not at all Satisfied	2	3 ©	4 O	5 O	6 ©	Very much Satisfied
How satisfie treatment?	d were you wi	th the availab	ility of staff to	discuss the te	echnical aspect	ts of your
Not at all Satisfied	2 ©	3 ©	4 ©	5 ©	6 ©	Very much Satisfied
	d are you with	your radiatio	n oncology ex	perience?		Vous and
Not at all Satisfied O	2 ©	3 ©	4 ©	5 ©	6 ©	Very much Satisfied