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The Fitzpatrick Skin Type Scale: A reliability and validity study in women undergoing radiation therapy for breast cancer

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1 TITLE

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5 ABSTRACT

Objectives: This study aimed to evaluate the internal consistency reliability and construct
validity of the Fitzpatrick Skin Type Scale during radiation therapy in a cohort of women
receiving treatment for breast cancer.

9 *Method:* The assessment of the Scale was performed as a nested study within a randomised
10 control trial of two creams used for radiation therapy skin care for breast cancer patients. The
11 sample consisted of 244 female patients undergoing radiation therapy for breast cancer.
12 Participants completed a modified version of the Fitzpatrick Skin Type Scale.

Results: Internal consistency as measured by the Cronbach's alpha was 0.505, 0.829 and 13 0.339 for the Genetic Disposition, Sun Exposure and Tanning Habits subscales respectively. 14 15 Only the Sun Exposure subscale surpassed the 0.70 cut off indicating good internal consistency. Maximum Likelihood factor analysis with promax rotation method confirmed 16 the *a priori* factor structure for the Sun Exposure subscale as well as providing evidence of 17 construct validity for this subscale. Analysis for the other two subscales highlighted issues 18 with internal reliability and construct validity suggesting that not all items on each subscale 19 20 truly measure the intended trait.

Conclusion: The study findings support reliability and validity of the Sun Exposure subscale
of the Fitzpatrick Skin Type Scale in a convenience sample of women receiving radiation
therapy for cancer. Despite limitations with two of the three subscales, this tool continues to
be used in clinical practice.

26 Key words

27 Fitzpatrick Skin Type Scale, Reliability, Validity

28

29 INTRODUCTION

Radiation therapy treatment for breast cancer has the potential to cause skin reactions such as 30 moist desquamation which adds to the distress associated with the patient's cancer diagnosis 31 and treatment.¹ Standardised grading tools, such as the Common Terminology Criteria for 32 Adverse Events (CTCAE) Version 4.0 2 are often used when assessing the skin condition of 33 patients undergoing radiation therapy. The skin reaction is graded from faint erythema or dry 34 desquamation (grade 1), to skin necrosis or ulceration of full thickness dermis (grade 4) on 35 the CTCAE. To minimise the severity of radiation-induced skin reactions, patients are often 36 37 advised to use various skin care products, such as a basic moisturising cream (100% sorbolene) but the effectiveness of any topical products in a tropical environment is yet to be 38 identified³ necessitating the need for further research. A randomised control trial (RCT) 39 investigating the effectiveness and acceptability of two skin care creams for patients 40 undergoing radiation therapy in a tropical region was therefore conducted. This RCT formed 41 the basis for the present nested study to assess the reliability and validity of the Fitzpatrick 42 Skin Type Scale (referred to in this paper as the Fitzpatrick Scale) in this group of patients. 43

44

45 BACKGROUND

In 1975, the Fitzpatrick Scale was developed to estimate the skin's response to ultraviolet (UV) light based on a person's sunburn and tanning experience.⁴ This scale has since been used widely to determine sun-reactive skin type and is currently the most commonly used tool or measure. It is recognised as the gold standard for classifying skin types.⁵ It consists of 3 subscales derived from a total of 10 items. Based on a total skin type score, respondents are 51 classified into 1 of 6 types (Skin type I-VI).⁴ The validity and reliability of this widely 52 utilised and accepted instrument is crucial as health and government agencies provide sun 53 protection and tanning advice based on this tool⁶⁻⁸ and because it has been applied in many 54 research studies.⁹⁻¹⁵

The Fitzpatrick Scale has been used mainly for assessing skin type as a potential confounder in clinical studies. Magin et al., ¹⁶ carried out a cohort study that examined the psychological complications of acne and used this scale to assess skin phenotype as a potential confounder in their study. Other dermatological studies have also utilised this classification system in determining the ability of an individual's skin type to act as a potential confounder when other outcomes are being assessed.¹⁶⁻¹⁷

Despite this widespread use, there are a limited number of studies that have examined the 61 reliability and validity of the Fitzpatrick Scale. The studies have examined the stability and 62 test-retest reliability of modifications of the scale with good results noted.^{7, 16, 18} The wide use 63 and acceptability of this instrument with no published studies on the internal consistency of 64 the items in the scale led to the current study reported in this paper. Magin et al., ¹⁶ recently 65 highlighted the lack of studies assessing the validity of this scale hence further necessitating 66 research in this area. We decided, therefore, to determine the internal reliability and validity 67 of the Fitzpatrick Scale in assessing skin type in patients receiving radiation therapy for 68 69 breast cancer in the tropics.

70

71 OBJECTIVE

To assess the internal consistency and construct validity of the Fitzpatrick Scale as a valid
and reliable tool for assessing skin type in women receiving radiation therapy for breast
cancer in the tropics.

76 MATERIALS AND METHODS

Setting: The assessment of the reliability and validity of the Fitzpatrick Scale was performed
as a nested study within a randomised control trial of two creams used in the skin care of
patients receiving radiation therapy for breast cancer in the tropics.

Sample: The data were collected from participants at the time of recruitment to the trial by a nurse between June 2010 and July 2012. As there were very few male participants the sample was restricted to the 245 female patients who provided informed consent to participate in the randomised control trial and completed the Fitzpatrick Scale. Data collection was completed by the recruiting nurse asking the questions and circling the boxes which best represented the participants' responses after showing them the scale. One woman was excluded from data analysis due to incomplete data hence the results are based on 244 women.

Instruments: The Fitzpatrick Scale is based on 3 concepts: genetic disposition or ancestry, reaction to sun exposure and tanning habits. The Genetic Disposition and Sun Exposure subscales consist of four items each and the Tanning Habits subscale consists of only two items, giving a total of 10 items. Participants are classified into 1 of 6 skin types based on their total skin type score (Table 1). This study used a version of the Fitzpatrick Scale similar to that available from the New South Wales Government website.¹⁹

93 INSERT TABLE 1

Ethics approval: Approval for the RCT from which this data were obtained was granted by
the XXXX (name to be provided) health service's human research ethics committee.

96 *Data analysis:* To estimate the internal consistency of the scores, the Cronbach's alpha 97 coefficient was calculated for each of the three subscales (Genetic Disposition, Sun Exposure 98 and Tanning Habits) based on the sample of 244 women. The aim was to determine if the 99 estimated coefficient values were acceptable according to the general convention in research 100 prescribed by Nunnally and Bernstein, ²⁰ who state that one should strive for reliability values 101 of 0.70 or higher. Classical item analysis was also conducted on the Fitzpatrick Scale to determine whether any items were negatively affecting the reliability of the subscales. The 102 next step was to conduct an exploratory factor analysis to identify the dimensions of the test 103 104 and more importantly to determine if multiple factors or traits underlie the items on each subscale. The Kaiser-Meyer-Olkin measure (KMO-test) was first conducted to determine 105 sampling adequacy with a value of >0.5 signifying adequacy. The Bartlett test of sphericity 106 was used to check for underlying structure to the data. This test has to be significant. 107 Maximum Likelihood (ML) was chosen as the method of extraction for the factor analysis 108 109 and the Scree test was used to determine the number of factors to retain for rotation. To simplify and clarify the data structure, the promax rotation method was applied. 110

111 The relationship between skin type and two possible influencing variables, ancestry and 112 dermatological history, were assessed for significance using the Chi square test of 113 Independence. The significance level was chosen as 0.05 and p values below this level were 114 regarded as statistically significant. The data were analysed using SPSS IBM statistics 115 version 19.

116 RESULTS

All participants were female with the majority being of Australian descent. The mean age was 55.5 years. About a quarter of respondents had a pre-existing dermatological condition ranging from allergies, psoriasis, eczema and other fungal skin diseases (Table 2).

120 INSERT TABLE 2

Almost half of the women reported having Skin type III with the minority having Skin Types
I and V. In our study, Skin type VI was not represented in the sample and so is not included
in the Table (Table 3).

124 INSERT TABLE 3

The Cronbach's alpha values for the three subscales of the Fitzpatrick Scale are presented in 125 Table 4. The Sun Exposure subscale has the highest alpha value of 0.829. The table also 126 features the Corrected Item-Total Correlation, Squared Multiple Correlation values and the 127 Cronbach's alpha if the weakest item is deleted from its subscale. The Corrected Item-Total 128 Correlation was low (<0.3) for three items in the Fitzpatrick Scale. In column six, for 129 example, removal of any item in the Genetic Disposition subscale except item "F1-Do you 130 have freckles on unexposed areas?" would result in a lower Cronbach's alpha. Conversely 131 removal of this latter item would lead to an improvement in Cronbach's alpha. It is also noted 132 133 that the corresponding Corrected Item-Total Correlation value was low (0.126) for this item.

134 INSERT TABLE 4

The KMO measure had a value of 0.783 signifying adequate sampling and the Bartlett test of 135 sphericity was significant (p<0.05). Exploratory factor analyses were performed and the 136 number of factors to retain was set manually at 2, 3 and 4 factors based on the Scree plot 137 (Figure 1) and the *a priori* factor structure. It is noteworthy to report that the general picture 138 of the factor analysis for each of the analyses was similar with respect to the item loading 139 pattern but retaining four factors had the best fit to the data in this study and this was selected 140 for the results (Table 5). The Sun Exposure subscale had all 4 items loading strongly on the 141 first factor while the 2 items for the Tanning Habits subscale loaded on the third factor. For 142 the Genetic Disposition subscale, the first 3 items loaded highly on the second factor except 143 item 4, "F1-Do you have freckles on unexposed areas?" which was the only freestanding item 144 in the Fitzpatrick Scale in this study loading on the fourth factor. 145

146 **INSERT FIGURE 1**

147 INSERT TABLE 5

148 The Chi square test for Independence showed no association between the Fitzpatrick Skin 149 Type and presence of a dermatological history in women (χ^2 =7.38, p=0.12). There was a statistically significant association between the Fitzpatrick Skin Type and the women's ancestry (χ^2 =32.30, p=0.02).

152

153 DISCUSSION

Prior to administering an instrument such as the Fitzpatrick Scale for research purposes, the validity and reliability should be assessed to facilitate the accuracy of the results obtained from the study. Assessment of the internal consistency of the Fitzpatrick Scale in this study showed Cronbach's alpha values below that expected for two of the three subscales with only the Sun Exposure subscale having the highest alpha value of 0.829 thereby satisfying the criterion for reliability.

Various reasons can be postulated for these results. There are a number of factors that can 160 affect the Cronbach's alpha value of a test, including how well the items in a test correlate to 161 each other and also the length of the test.²¹ Correlation in a test refers to extent to which all 162 items measure the same thing.²² It is not certain for the Fitzpatrick Scale whether each test 163 item truly measures the same trait on the same subscale as observed by the low item-total 164 correlation values. Therefore to determine how well the items on the test correlate, an 165 exploratory factor analysis was applied.²¹ The exploratory factor analysis also provides an 166 assessment of the correctness or incorrectness of the factor structure.²³ We performed a series 167 of exploratory factor analyses based on the method described by Costello & Osborne.²³ They 168 described a clean factor structure as one with item loadings above 0.30, no or few item 169 crossloading and no factors with fewer than three items. Retaining 4 factors showed that all 170 items on the Sun Exposure subscale loaded together on a single factor and factor loadings 171 were high. This can be considered to be a good factor structure. This subscale appears to 172 correspond to the above criteria and also has a Cronbach's alpha value suggestive of good 173 reliability. For the Tanning Habits subscale, both items loaded together on a single factor but 174

175 as the number of items in this subscale is only two, this should be interpreted with caution as both the alpha values and item-total correlations are below that accepted. This factor is 176 therefore considered weak and unstable.²³ We suggest including more items to this subscale 177 to strengthen reliability of the Fitzpatrick Scale in a similar population. Also in response to 178 the two items on this subscale which ask "When did you last expose your body to the sun (or 179 artificial sunlamp/tanning cream)?" and "Did you expose the area to be treated to the sun?" it 180 is likely that a considerable number of women had exposed their breasts to the sun in the past. 181 Since many of the respondents were 'Baby Boomers', (that is, born between 1946 and 1964), 182 they grew up in a time when experimenting with topless sunbathing and swimming was 183 common in sunny climates such as North Queensland. The questions refer to exposure to the 184 sun or artificial tanning and it is difficult to classify exposure, for example, in participants 185 186 who swam in their own pools topless, but only in the shade. It is important to note also that in a place like North Queensland, parts of the bodies are exposed to the sun every day incidental 187 to other activities, so the first item on this subscale is also problematic in that way. The term 188 189 "tanning cream" also created some confusion as to its meaning. Respondents asked whether this included spray tans or even solariums. 190

The Genetic Disposition subscale appears to have one of the four items loading on a different 191 factor. This item "Do you have freckles on unexposed areas?" is not well loaded onto the 192 factor representing its subscale. This item is also the weakest on the subscale with a low item-193 194 total correlation and does not appear to correlate with the other items that are well loaded on this subscale. The other 3 items on this subscale relate to measurement of eye, hair and skin 195 colour which appear to measure a single construct as they are constant traits. Although 196 freckles are an inherited trait and therefore classify as a genetic factor, they can also be non-197 inherited arising following sun exposure making them an acquired trait.²⁴ This item was also 198 noted by the recruiting nurse as problematic for women who gave other responses such as 199

"few" and "incidental". These responses may explain the inability of this item to load on the same factor with other items in the *a priori* factor structure. We suggest removing this item from the subscale due to its free standing nature or adding items measuring similar traits to form a new subscale to be examined in future studies.²³

As stated earlier in this section, the measured alpha value also depends on the test length, 204 with shorter tests generally having a lower alpha value.²⁵ The Fitzpatrick Scale has 10 items 205 in total and can be considered a short test. Hence the alpha values should be interpreted with 206 some degree of caution. Tests with 20 items or more will have acceptable Cronbach's alpha 207 208 values even though they may be measuring multiple characteristics. Close examination of the item-total correlations is recommended with values ranging from 0.15 to 0.20 for scales 209 measuring broad characteristics and 0.40 to 0.50 for those measuring less widespread traits.²⁵ 210 According to Nunnally & Bernstein,²⁰ acceptable item-total correlation is >0.30 for all items 211 with most being >0.5. Items with values less than 0.3 should be examined closely as they 212 may have little to do with the subscale. The item "Do you have freckles on unexposed 213 areas?" has the lowest item-total correlation along with the two items in the Tanning Habits 214 subscale. 215

The Cronbach's alpha results and the exploratory factor analysis provide some evidence of 216 construct validity for the Fitzpatrick Scale mainly in regards to the Sun Exposure subscale 217 which we rate as good. For the Genetic Disposition subscale, the construct validity can be 218 rated as fair because all items except one load on the same factor and have factor loadings 219 >0.3 considered acceptable for the minimum loading of an item.²³ The results suggest that the 220 Tanning Habits subscale should be removed from the Fitzpatrick Scale as it is very difficult 221 to interpret results with only two items in this subscale; hence one item may not necessarily 222 provide more information than the other when trying to elicit patients' tanning habits. 223

In this study there was a statistically significant association between the Fitzpatrick Skin 224 Type of women and their ancestry. Other evidence available also suggests a relationship 225 between a person's skin type and country of ancestry.²⁶ People with skin types I, II and III 226 tend to be of English, Scottish or Scandinavian descent as compared to people with skin types 227 V and VI who originate mainly from middle eastern, Indian and African countries. There was 228 no association between the Fitzpatrick Skin Type and presence of dermatological history 229 although studies have shown a relationship between skin type and some dermatological 230 conditions. People with skin types IV-VI are more prone to developing acne vulgaris 231 compared to the other skin types.²⁷ Various studies have shown that people with fair skin are 232 at risk for developing basal cell carcinoma as well as those with Fitzpatrick Skin Type II.²⁸ 233 The relationship between the Fitzpatrick Skin Type and skin reactions such as moist 234 desquamation following radiation therapy in cancer patients were reported in two previous 235 studies.^{29,30} The findings of the RCT within which this study was nested have recently been 236 published.³¹ 237

238

239 LIMITATIONS

The results of this study provide some evidence to support the reliability and validity of the 240 Fitzpatrick Scale although there were a number of limitations. All participants are females 241 limiting the generalisability of the findings. A further limitation is the utilisation of a version 242 of the scale which has a risk of modifying the original content but this version is from a 243 credible source utilised in Australia and cited in other publications. As noted earlier, the few 244 studies that have evaluated reliability and validity of modifications of the Fitzpatrick Scale 245 have reported good results. Although these results are based on the test retest reliability of the 246 Scale, estimation of this was not feasible in the RCT because of heavy respondent burden for 247 completion of other surveys. There is also a potential for information bias occurring as a 248

result of the way in which the Fitzpatrick Scale was administered due to the use of several
data collectors. However the inter-rater reliability among data collectors was assessed prior to
the study commencement and was high (95% concordance).

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253 CONCLUSIONS

Considering the importance of skin type and how frequently the Fitzpatrick Scale is used, the 254 findings from the study hold merit because the Sun Exposure subscale has been rated 255 specifically to have a good internal consistency and construct validity. Overall, the tool is 256 257 easy and quick to administer in the clinical environment with practical application for patient education and information sessions. If the Fitzpatrick Scale is included as part of the routine 258 assessments associated with planning for radiation therapy, clinical staff can inform patients 259 260 prior to commencement of radiation therapy that they may be more or less likely to develop acute skin reactions if they fall into a particular Fitzpatrick Skin Type. 261

As the alpha value from a test is dependent on the specific sample of respondents, ²¹ replication of the analysis is recommended on other samples. Also, because there are no published studies examining the internal consistency and construct validity of the Fitzpatrick Scale, we are unable to compare our findings but suggest that further research is imperative to enhance the accuracy of assessments using this scale.

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268 ACKNOWLEDGEMENTS

Funding for the RCT, for which the Fitzpatrick Scale was used, was received from the
Townsville Health Service District Private Practice Research and Education Trust Fund
(2009, 2010, 2011), and a Queensland Health Nursing and Midwifery Research Grant 2009.
We also acknowledge the following nurses who were principal data collectors at various

273	stages throughout this study: Nadine Laffin, Gail Abernethy, Elizabeth Heyer, Vanessa Evans
274	and Kellie West.
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276	DECLARATION OF INTEREST
277	None.
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TABLES

Table 1 Fitzpatrick Skin Type Classification

Skin Type	Score	Overall skin type descriptor		
Ι	0-6	Always burns, never tans		
		(pale white skin)		
II	7-13	Always burns easily, tans		
		minimally (white skin)		
III	14-20	Burns moderately, tans		
		uniformly (light brown skin)		
IV	21-27	Burns minimally, always tans		
		well (moderate brown skin)		
V	28-34	Rarely burns, tans profusely		
		(dark brown skin)		
VI	35+	Never burns (deeply		
		pigmented dark brown to		
		black skin)		

Source: Australian Government, 2012. Australian Radiation Protection and Nuclear Safety Agency

Variable	Results: n (%)
Age in years: mean (SD)	<mark>55.5 (11.7)</mark>
Indigenous status	13 (5.3)
Place of birth/Ancestry	
Australia	203 (83.2)
Europe	20 (8.3)
Asia	8 (3.3)
NZ	<mark>4 (1.6)</mark>
USA	1 (0.4)
Not specified	8 (3.3)
Presence of dermatological condition	59 (24.4)

Table 2 Demographics and smoking patterns of sample ($N=\frac{244}{244}$)

SD: Standard Deviation; NZ: New Zealand; USA: United States of America

	Type I	Type II	Type III	Type IV	Type V	Total
Ancestry						
Australia	7 (2.9)	65 <mark>(26.6)</mark>	<mark>83 (34.0)</mark>	41 <mark>(16.8)</mark>	7 (2.9)	<mark>203 (83.2)</mark>
NZ	0 (0)	0 (0)	3 (1.2)	<mark>1 (0.4)</mark>	0 (0)	<mark>4 (1.6)</mark>
Europe	0 (0)	2 (0.8)	12 (4.9)	4 (1.6)	2 (0.8)	20 (8.3)
USA	0 (0)	0 (0)	1 (0.4)	0 (0)	0 (0)	1 (0.4)
Asia	0 (0)	1 (0.4)	1 (0.4)	6 (2.5)	0 (0)	8 (3.3)
Not	0 (0)	0 (0)	3 (1.2)	5 (2.0)	0 (0)	8 (3.3)
specified						
Total	7 (2.9)	68 <mark>(27.9)</mark>	<u>103 (42.2)</u>	<mark>57 (23.4)</mark>	9 (3.7)	244 (100)
Age group						
27-34	0 (0)	0 (0)	1 (0.4)	2 (0.8)	2 (0.8)	5 (2.1)
35-44	2 (0.8)	9 (3.7)	9 (3.7)	9 (3.7)	0 (0)	29 (12.0)
45-54	3 (1.2)	21 (8.7)	<mark>32 (13.1)</mark>	23 (9.5)	4 (1.7)	<mark>83 (34.0)</mark>
55-64	0 (0)	22 (9.1)	29 (12.0)	<mark>10 (4.1)</mark>	2 (0.8)	<mark>63 (25.8)</mark>
65-74	2 (0.8)	12 (5.0)	27 (11.2)	12 (5.0)	1 (0.4)	54 (22.3)
75-84	0 (0)	4 (1.7)	5 (2.1)	1 (0.4)	0 (0)	10 (4.1)
Total	7 (2.9)	68 <mark>(27.9)</mark>	103 (42.2)	57 (23.4)	9 (3.7)	<mark>244</mark> (100)

Table 3 Skin type by Ancestry and Age group (in years) n (%)

NZ: New Zealand; USA: United States of America

*Note Skin Type VI is not represented in the sample

Table 4 Classical Item Analysis

Subscale	Cronbach's	Items	Corrected	Squared	Cronbach's
	Alpha value		Item-Total	Multiple	Alpha if Item
	for subscale		Correlation	Correlation	deleted*
Genetic	0.505	F1-What is the	0.399	0.207	0.325
Disposition		colour of your			
		eyes?			
		F1-What is the	0.341	0.146	0.402
		natural colour of			
		your hair?			
		F1-What is the	0.382	0.191	0.375
		colour of your			
		skin (non			
		exposed areas)?			
		F1-Do you have	0.126	0.017	0.601
		freckles on			
		unexposed areas?			
Sun	0.829	F2-What happens	0.646	0.438	0.791
Exposure		when you stay in			
		the sun too long?			
		F2-To what	0.763	0.636	0.731
		degree do you			
		turn brown?			

		F2-Do you turn	0.704	0.580	0.764
		brown within			
		several hours of			
		sun exposure?			
			0.506	0.20 (0.022
		F2-How does	0.536	0.306	0.833
		your face react to			
		the sun?			
Tanning	0.339	F3-When did you	0.218	0.047	Not
Habits		last expose your			Applicable
		body to sun (or			
		artificial			
		sunlamp/tanning			
		cream)?			
		F3-Did you	0.218	0.047	Not
		expose the area to			Applicable
		be treated to the			
		sun?			

*when weakest item is removed from each subscale

Table 5 Exploratory Factor Analysis Pattern Matrix: Four Factor Solution

Items		Factor				
	1	2	3	4		
F1-What is the	-0.144	0.755	-0.007	0.102		
colour of your eyes?						
F1-What is the	0.057	0.479	0.005	0.184		
natural colour of						
your hair?						
F1-What is the	0.302	0.496	-0.028	-0.070		
colour of your skin						
(non-exposed areas)?						
F1-Do you have	0.105	0.133	0.065	0.362		
freckles on						
unexposed areas?						
F2-What happens	0.819	-0.048	-0.038	0.303		
when you stay in the						
sun too long?						
F2-To what degree	0.844	-0.003	0.063	-0.110		
do you turn brown?						
F2-Do you turn	0.764	0.025	0.028	-0.218		
brown within several						
hours of sun						
exposure?						

F2-How does your	0.663	-0.046	-0.053	0.255
face react to the sun?				
F3-When did you last	-0.018	0.006	1.007	0.089
1'5- when did you last	-0.010	0.000	1.007	0.007
expose your body to				
our (or ortificial				
suii (or artificiai				
sunlamp/tanning				
cream)?				
F3-Did you expose	0.099	-0.071	0.202	-0.229
the area to be treated				
to the sun?				





Figure 1 Scree plot for determination of number of factors retained for rotation