Validating a New Tool on Assessment of Fulfilment of Expectations of Patients with Non-Communicable Diseases – An Ordinal Data Analysis Approach

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Abstract

Introduction: Fulfilment of expectations and attitude to treatment in OPD set-up is an important indicator for quality of service delivery, which is even further important for patients with non-communicable diseases (NCDs) since it will lead to better adherence – a key concept in comprehensive management of any NCD.

Objectives: The current study was carried out to establish internal consistency reliability &construct validity and dimensionality of the new tool.

Methods: The new pre-tested tool had 26 items each being a three-point likert-type item. Temporal method of sampling was followed for interviewing the respondents meeting inclusion and exclusion criteria. Taking an item-to-respondent ratio of 1:5, minimum sample size of 130 was calculated. Internal consistency and construct validity were measured by ordinal Alpha and ordinal Omega coefficients with more emphasis on later. Multiple correspondence analysis (MCA) was performed assuming ordinal level of categorical response for each item using the software R (version 3.3.0).

Results: 131 completed responses were analysed. Majority were aged below 40 years, male and Hindu. Diabetes Mellitus and hypertension were the major diagnoses. Ordinal Alpha was 0.67 (95% CI: 0.6 – 0.74) and ordinal Omega (total) was 0.72 (95% CI: 0.65 – 0.79). On MCA 6 dimensions were retained in accordance with the conceptual framework. Time-intensiveness was first dimension as it explained maximum variance (18.28%). The items had relatedness to different dimensions measured by η^2 value.

Conclusion: The study concluded with strong evidence of internal consistency and construct validity of the tool with ordinal level of items. Items having bearing on multiple dimensions in the MCA solution revealed the relatedness of the dimensions. However, with more resources a multi-centric multi-OPD study can be planned for more precise estimates.

Keywords: Multiple Correspondence Analysis, Ordinal data, Validation, Internal Consistency, Fulfilment of patient expectations

1. Introduction

Establishing validity and reliability of a study tool is one of the very important parts in conducting a clinical research.[1– 4] However in healthcare settings attitude towards treatment provided combined with fulfilment of expectations not only indicates service quality and acceptance but provides very crucial information regarding adherence and future care-seeking behaviour[5], which is a very important element in management of non-

communicable diseases (NCD)[6] Thus a tool which measures these constructs in a valid precise way can lead to proper conclusion regarding level of care especially dedicated to NCD patients. Several tools [7 – 9] exist for assessment of satisfaction at out-patient clinics in foreign settings. Therefore a validated Indian tool is required for assessment of fulfilment of expectations especially in the context of increasing non-communicable diseases [10] in India.

As seen with many tools in behavioural science research, establishing validity is a very challenging issue, nevertheless a very important one. [11] The current study was therefore carried out to establish internal consistency reliability &construct validity and dimensionality of the new tool among the patients suffering from non-communicable diseases.

2. Methodology

2.1 Development of the tool:

Items were developed based on dimensions identified through themes generated from 14 in-depth interviews conducted among patients (who were excluded from the main study), and literature review of similar articles [12 – 15] and scales [7 – 9]. In order to quantify, each of the six dimensions comprised of several items rated on a scale comprising of three-point [16] likert-type items [17, 18]. It was presumed the items from one dimension may have bearing on other dimension(s) as well. By conducting pre-testing among a separate group of patients seeking out-patient care in the same setting the 26 item tool was finalized. Individual items from these 26 items had bearing on specific dimensions (FIGURE 1), though the relatedness to other dimensions was also presumed.

2.2 Data collection

After obtaining relevant permissions, consenting individuals, not critically or terminally ill and not having detected with carcinoma, diagnosed with at least one of the major non-communicable diseases (hypertension, diabetes mellitus, arthritis, COPD)[19,20] attending general medicine OPD of a tertiary care hospital in Kolkata for follow-up visit during the month of April, 2017, having had minimum one follow-up earlier for the ongoing episode(s) of disease(s) were interviewed with the pretested study tool. The responses were noted and compiled into a dataset using the pre-defined codes with the help of EpiInfo 7.2. The new scale consisted of 26 items. A minimum sample size of 130 (item: respondent taken as 1:5[21, 22]) was calculated. Samples were drawn in a temporal pattern [23]. In the selected OPD the follow-up patients are usually reviewed after 4 weeks; therefore 4 weeks in the month of April (3rd April to 30th April) were selected for data-collection. The OPD hours were from 9:00 am to 2:00 pm every day in a week with no OPD on Sunday. In order to get a representative sample of NCD patients attending General Medicine OPD, respondents were chosen from six OPD days with two days chosen per week randomly.

For example, in the first week, two separate days from Monday to Saturday were selected at random. In the next week similarly two days excluding the already selected two days were selected at random. Finally in the third week the remaining two days were used. On all the days 5 hours were available for data-collection. For six days total hours of data collection added up to 30 hours. It was computed that per hour maximum $130/30 \approx 5$ patients were to be interviewed. If in an hour less than 5 patients were interviewed, in the next hour(s) still maximum 5 individuals were to be interviewed. First 5 patients (maximum) complying with the inclusion and exclusion criteria were interviewed every hour during OPD duration on the selected days, yielding 117 individuals interviewed at the end of third week. The fourth week was kept to reach the minimum sample size in case it was not fulfilled

in the planned six days. One day was therefore selected randomly on the fourth week and data collection was done maintaining maximum 5 individuals/ hour norm, which gave the final sample size of 131 individuals. Analysis was done on these 131 samples.

2.3 Method of analysis:

Commonly Cronbach's alpha is a measure used to report reliability of a scale by measuring internal consistency [24]. But Cronbach's alpha can only be computed with a meaningful result if the scale measurements are continuous [24, 25]. In the present study items were constructed on a three point likert-type scale. The results for each item were considered not consistent with the assumption of underlying continuality [26, 27], but ordinal with three levels [25, 28]. In order to report internal consistency reliability of the 26-item scale we used ordinal alpha [29,30] and ordinal gamma coefficients [29], computed with the help of R statistical software (R version 3.3.0). Having all ordinal items in the scale Multiple Correspondence Analysis (MCA) was used with the help of "FactoMineR" package [31] as a principal component method (non-linear) [32 – 34] to reduce the items to six dimensions with major explained variability. Effect of the six dimensions was considered during development of the tool and their contributions, level of explained variability has been reported. Since the objective was to explore the dimensionality and discrimination among items, the results pertaining to variables were considered. Relatedness of the variables to the dimensions considered for analysis were calculated by η^2 value obtained from the analysis. The relatedness of the items to dimensions helped in identifying the dimensions in concordance with those of the conceptual framework. Since the objective was to explore the reliability and validity of the 26 items scale, all the items (categorical variables) were entered in the MCA model as active variables without taking any supplementary variables into consideration, since supplementary variables do not contribute in building the dimensions.

3. Results & Discussion

3.1 Socio-clinical characteristics:

Among the 131 individuals interviewed with the help of this study tool, majority were aged within the first quartile (26%) i.e. below the age of 40 years. The age range was from 24 years to 75 years with a mean of 51.63 years (SD 12.14 years) and median age 53 years. Majority were male (60.3%), Hindu (59.5%) population residing mainly in urban areas (municipality 22.9%, corporation area 30.5%). A major proportion of the study participants were illiterate (25.2%) and only able to sign (just literate – 11.5%). More than half of the sampled population (70.2%) were performing sedentary work. Proportions of nuclear and joint family background were almost equal (joint – 50.4%). (TABLE 1)

Majority of the patients were diagnosed with at least Hypertension, followed by at least Diabetes Mellitus. The distributions of the diagnoses are presented in Figure 2 in the form of a Venn diagram. 44 of the patients had only hypertension while 47 had only diabetes with 16 having both. No one was suffering from COPD only, though 6 patients visited the General Medicine OPD with diagnosis of Arthritis only. Only 2 patients had been diagnosed with diabetes, hypertension and COPD. None of the patients had been diagnosed with all of the four NCDs considered. (FIGURE 2)

3.2 Internal consistency and construct validity:

As a measure of reliability value of Omega has been considered more important since the scale comprise of ordinal items, and thus ordinal Alpha is prone to under-report reliability. [28] Ordinal Cronbach's Alpha measured for the 26 items scale was 0.67 (95% CI: 0.60 – 0.74). A similar measure of scale reliability and construct, total

ordinal Omega was 0.72 (95% CI: 0.65 – 0.79). (FIGURE 3)

Since analysis was done on ordinal items, median and mode were reported as central tendency measures in Table 2. If item-deleted values of both ordinal Alpha and Omega for each item was computed and reported in the table. Iterations to compute estimates assuming ordinal level for the questions if each of question 2, 18 or 22 were deleted separately from the scale did not converge (after 1000 iterations). Therefore reliability statistics for scale if any of those items were individually deleted could not be computed. For the remaining items item-deleted scale's ordinal Cronbach's Alpha showed improvement from the observed value (0.67) for every item. If item 5 or item 11 were removed from the scale with current observations, ordinal Alpha showed major improvement (ordinal Alpha if item deleted = 0.74). However, while considering the total ordinal Omega value for majority of the items, the item-deleted scale values were lower than actually observed value (0.72). Scale Omega value if item 4, 12, 13 or 24 was deleted, found to be higher in each case, with highest value (0.75) if item 4 or 12 was deleted. (TABLE 2)

3.3 Exploring principal components – Multiple correspondence analysis

Keeping parity with the conceptual framework 6 dimensions were retained as the line diagram showing percentage of variance explained by dimensions did not produce any steep change in slope after dimension 6 (6.38% explained variance) was obtained. Dimensions identified from the analysis were tallied with the dimensions in the conceptual framework (FIGURE 1 and TABLE 3 comparative assessment was done before labelling dimensions).Time-intensiveness for OPD visit was identified as the Dimension 1 (explaining maximum variability 18.28%), followed by Behaviours of staffs &

communication skill as Dimension 2 (16.93% explained variability). Cost (12.17%) &Attitude towards treatment compliance in the system (8.09%) were identified as Dimensions 3 & 4 respectively. Trust in the system (6.83% explained variability) was regarded as the penultimate dimension with Infrastructural set-up being the last dimension retained. (FIGURE 4)

The relatedness of the items to the dimensions as shown in Table 3 clearly suggest that the dimensions in the MCA model are not only overlapping but a non-linear combination is also more logical. Items 1 to 4 and 17 showed good relatedness to Behaviour dimension. From the η^2 values reported, discrimination amongst the variables can also be understood. Items 1 to 4 and 17 had good discrimination in all the dimensions except the infrastructural set-up. Items 7 to 9 conceptually belonging to time dimension showed good relatedness to the time-dimension (dimension 1) retained from MCA model. They had good relatedness to behaviour dimension though their discrimination on that dimension was poor. Items 11, 12 and 13 were cost-related questions having good statistical bearing on the cost dimension with low discrimination over time-dimension. Items 21 to 26 belonging to compliance dimension in the framework reported good relatedness with discrimination, though item 21 had better relatedness to cost dimension. Items 14 to 16 and 18 to 20 belonged to trust dimension, however items 14 to 16 had better relatedness to cost-dimension. Items 14, 16 and 18 also had good η^2 values for time-dimension and items 14, 16 also on infrastructure dimension (dimension 6). Item 18 was though better related to compliance dimension. Items 5, 6 and 8 were related to the last dimension, but η^2 values for item 5 were higher for cost, compliance and trust dimensions. (TABLE 3)

MCA factor maps considering pairs of dimensions were produced and 20 categories with major contributions (in

building the dimensions) are shown in FIGURE 5. Though original factor maps contained all the categories from all the items, but for representation major contributing categories were plotted. The categories were distributed around the centre. Those distant from the centre represent comparatively rarer response. In figure 5.(A) excluding the first category responses of items 1, 3, 17, 14 rest of the 16 presented categories were almost symmetrically distributed around the centre. Similarly in figure 5.(B) and 5.(C) symmetry can be noted. The plotted categories appear further compact in figures 5.(B) and 5.(C).

3.4 Discussion:

Use of MCA as a principal component method is possible, though not frequently practised. Since the objective was to validate the scale with three-point likert-like responses for each item, MCA was used to identify the non-linearly combined principal components from an array of categorical data. Ordinal measures for construct validity were at the satisfactory level. Ordinal Omega however is more important than the ordinal alpha calculated, since it is a useful lower bound statistic for categorical data analysis. During calculating the measures with single item deleted, the ordinal alpha showed improvement in every case, though ordinal Omega did not. Since the items were aligned with the conceptual framework, no further deletion was performed after getting an acceptable range of construct validity (Ordinal Alpha: 0.67, Ordinal Omega: 0.72).

Traditionally Cronbach's Alpha is not a measure of uni-dimensionality [35]. The calculations of construct validity measures provide a measure of greatest lower bound

values, where ordinal Omega is more important and informative comparted to ordinal Alpha. Dimensions explored established the stability of the tool. Six dimensions were retained in the final MCA model as per the conceptual framework of questionnaire development. Since the first dimension explained maximum variance in the scale, not only the items pertaining to it had good η^2 value, but several other related items also reported good relatedness to the dimension. As evident in Figure 5, the span of major contributing categories were more when plotted between the first two dimensions (categorical principal components). The plot became compact when the last two dimensions were considered. Since the last two dimensions accounted for a lesser percentage of variability, the plot of major contributing categories also came closer to the centre. While performing MCA Burt matrix was used instead of the default Indicator matrix. This resulted in a better explained variability percentage, but the dimensional solutions remained the same.

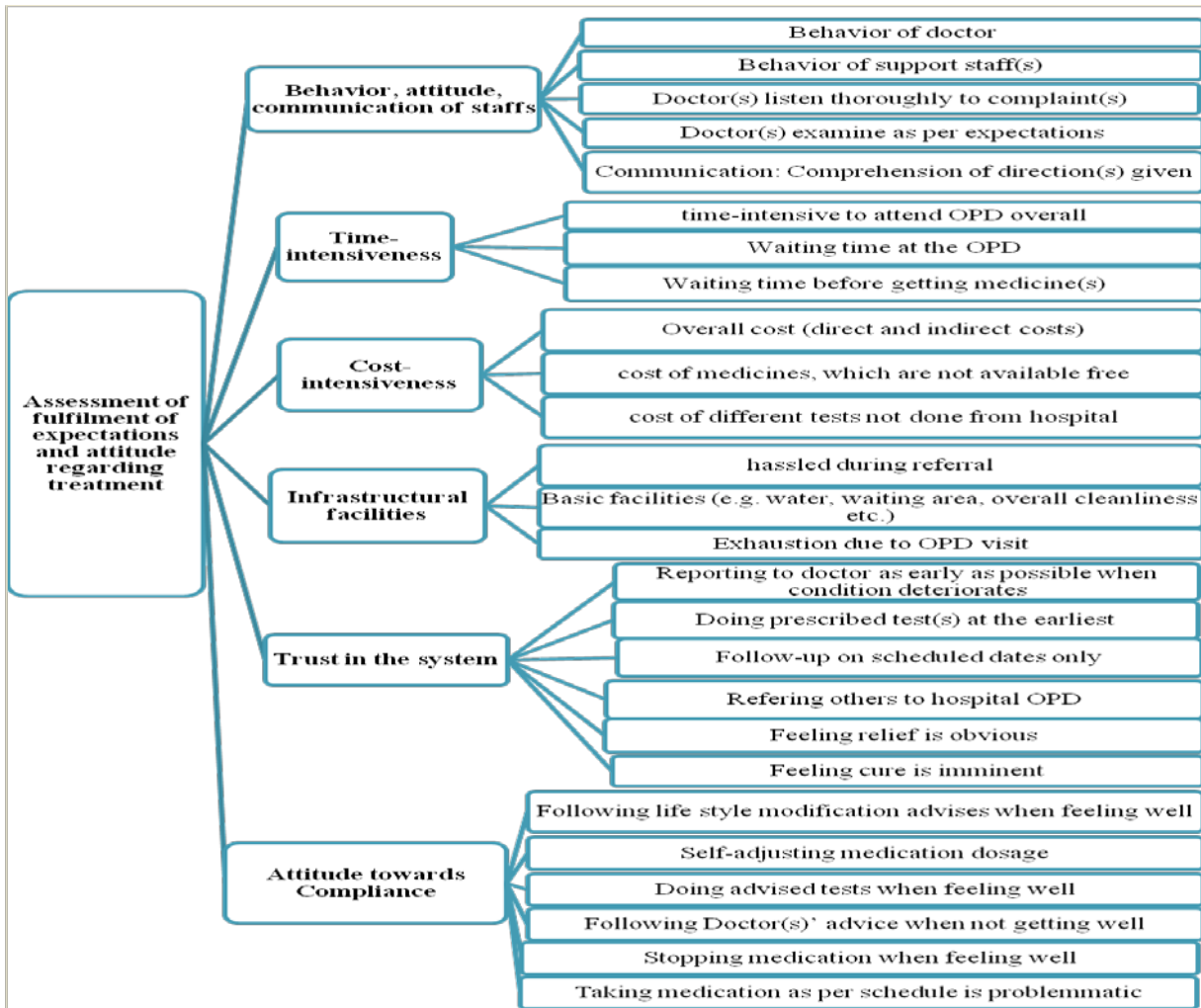**Figure 1: Conceptual Framework of item-generation to assess fulfilment of expectation and attitude.**

FIGURE 2 – Diagnosis of the different non-communicable diseases among the respondents. (n=131).
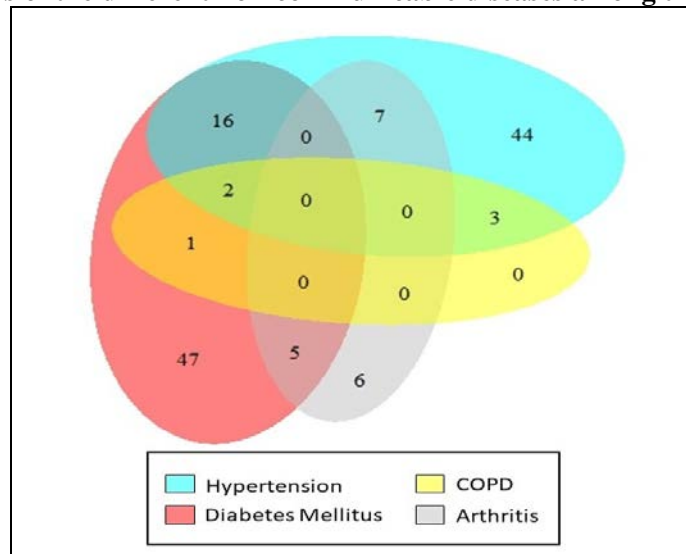
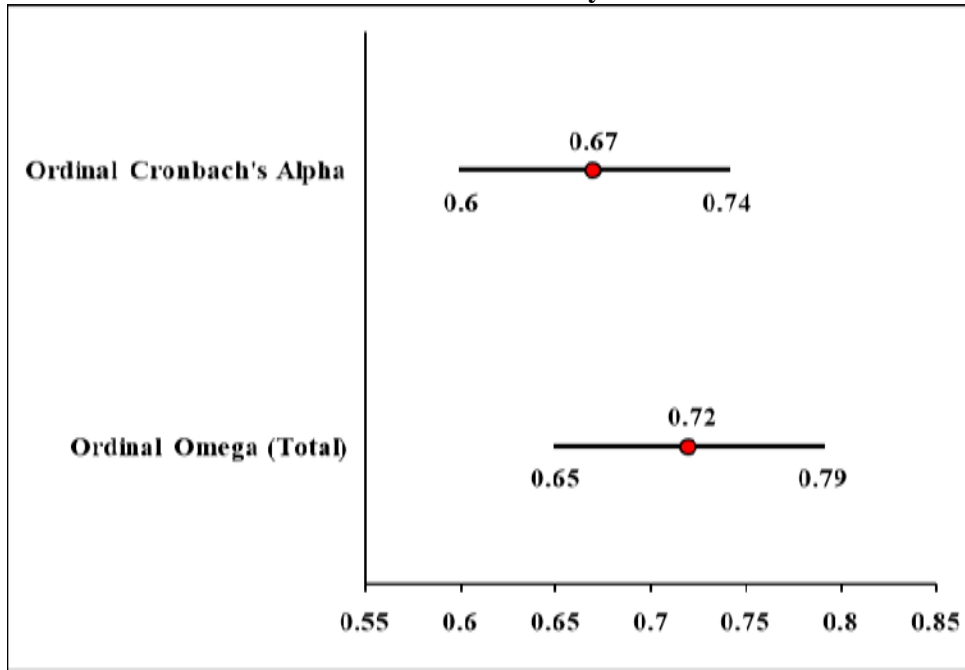**FIGURE 3 – Measures of internal consistency of the 26 item ordinal scale.**

FIGURE 4 – Variability (variance) in overall scale-response explained by individual dimensions.
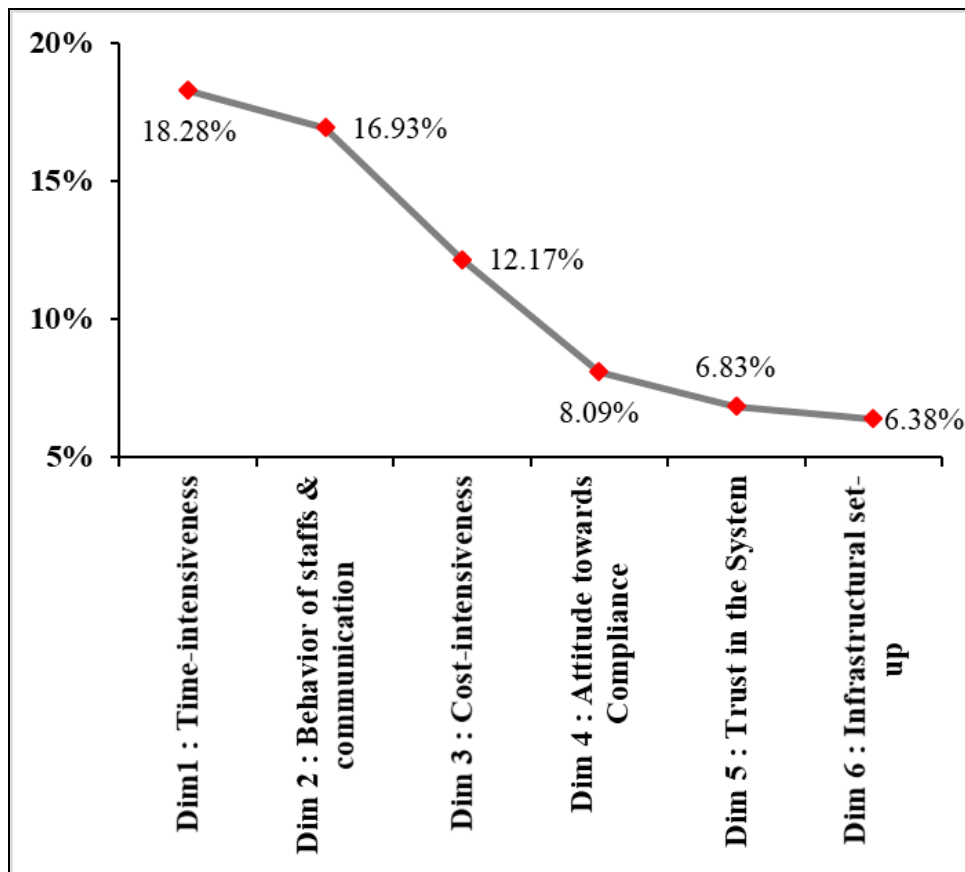
FIGURE 5 – MCA factor map of item categories with 20 categories having maximum contributions.
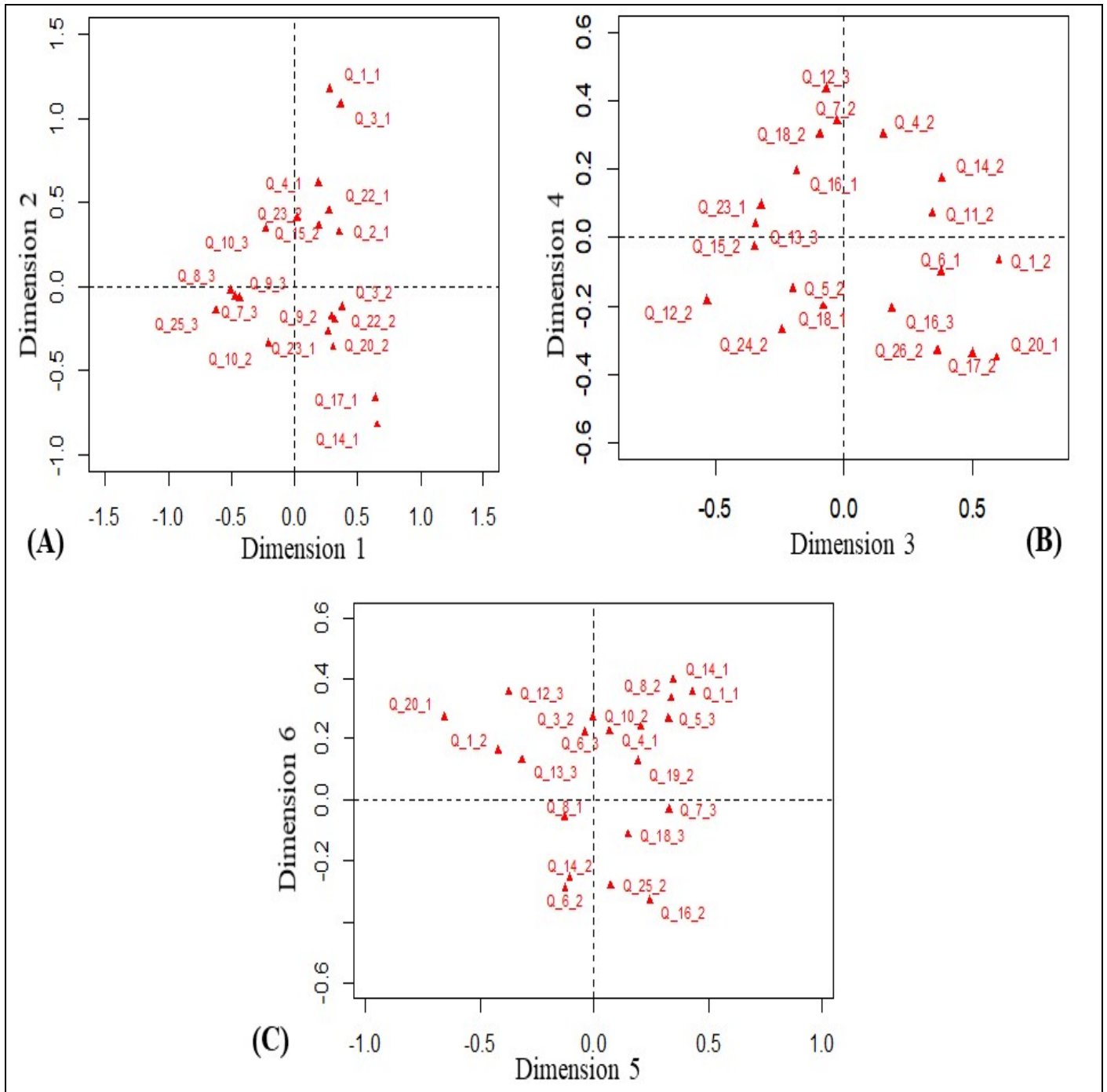
TABLE 1 – Socio-demographic background of the study participants. (n = 131)

Sl. No.	Variables	Category of the variable	Frequency (Percentage)
1.	Age	< 40 years	34 (26.0)
		40 – 53 years	33 (25.2)
		53 – 60 years	32 (24.4)
		≥ 60 years	32 (24.4)
2.	Gender	Male	79 (60.3)
		Female	52 (39.7)
3.	Religion	Hinduism	78 (59.5)
		Islam	53 (40.5)
4.	Area of Residence	Panchayat	61 (46.6)
		Municipality	30 (22.9)
		Corporation	40 (30.5)
5.	Level of Education	Illiterate	33 (25.2)
		Just Literate	15 (11.5)
		Below Primary	10 (7.6)
		Primary	17 (13.0)
		Middle	28 (21.4)
		Secondary	23 (17.6)
		Higher Secondary	5 (3.8)

6.	Type of Family	Nuclear	65 (49.6)
		Joint	66 (50.4)
7.	Physical Activity	Non-Sedentary	39 (29.8)
		Sedentary	92 (70.2)

TABLE 2 – Item-specific response-summary and measures of ordinal-scale reliability with deleted item. (n=131)

Items in the questionnaire	Median	Mode	Ordinal Cronbach's Alpha if Item Deleted	Ordinal Omega (Total) if item Deleted
1. The Doctor(s) behave with me as per my expectations	3	3	0.69 (0.62 - 0.77)	0.72 (0.65 – 0.79)
2. The behavior of the support stuff(s) is as per my expectations	2	3	--[a]	--[a]
3. The Doctor(s) listen thoroughly to my complaint(s)	3	3	0.68 (0.6 – 0.76)	0.69 (0.61 – 0.76)
4. The Doctor(s) examine me as per my expectations	3	3	0.73 (0.66 – 0.79)	0.75 (0.69 – 0.81)
5. I feel hassled when referred to another room/facility from this OPD*	2	1	0.74 (0.67 – 0.8)	0.68 (0.61 – 0.76)
6. The cleanliness and basic facilities (e.g. water, waiting area etc.) at OPD are up to the mark	2	3	0.73 (0.67 – 0.8)	0.7 (0.63 – 0.77)
7. It is time-intensive to attend OPD*	1	1	0.7 (0.62 – 0.77)	0.67 (0.62 – 0.77)
8. The waiting time before OPD is much more than my expectation*	1	1	0.71 (0.64 – 0.78)	0.66 (0.58 – 0.74)
9. The waiting time for getting the medicines from pharmacy is as per my expectations	2	1	0.71 (0.64 – 0.78)	0.66 (0.58 – 0.74)

10. I feel exhausted when I come to visit OPD*	2	1	0.7 (0.63 – 0.77)	0.67 (0.59 – 0.75)
11. I feel treatment at OPD is costly for me (direct and indirect costs)*	3	3	0.74 (0.67 – 0.8)	0.68 (0.61 – 0.76)
12. It is difficult for me to afford the cost of medicines, that are not available free	1	1	0.72 (0.65 – 0.79)	0.75 (0.69 – 0.81)
13. It is difficult for me to afford the cost of different tests that I have to get done from outside*	1	1	0.7 (0.63 – 0.77)	0.73 (0.66 – 0.79)
14. I tell others to attend OPD for their illnesses, that I feel cannot be handled at the local level	3	3	0.7 (0.62 – 0.77)	0.67 (0.59 – 0.75)
15. I am confident that relief is obvious when I visit the OPD	3	3	0.74 (0.67 – 0.8)	0.68 (0.6 – 0.75)
16. I feel cure is imminent when I visit the OPD	2	1	0.72 (0.65 – 0.78)	0.66 (0.58 – 0.74)
17. I don't understand the directions given by the doctor including the schedule to take medications*	3	3	0.7 (0.63 – 0.77)	0.65 (0.57 – 0.73)
18. I shall report to my doctor as early as possible when my condition deteriorates	2	1	-- [a]	-- [a]
19. I shall do prescribed test(s) at the earliest	2	1	0.73 (0.67 – 0.8)	0.68 (0.61 – 0.76)
20. I shall visit the Doctor on the dates I'm called for follow up	3	3	0.71 (0.64 – 0.78)	0.65 (0.57 – 0.73)
21. I shall stop following the life style modification advises when feeling well*	3	3	0.73 (0.66 – 0.79)	0.67 (0.6 – 0.75)
22. I shall cut down the dosage of my medication on my own*	3	3	-- [a]	-- [a]
23. I shall stop taking my medication when I am feeling well*	3	3	0.7 (0.63 – 0.77)	0.66 (0.58 – 0.74)
24. I shall stop following Doctor(s)' advice if I'm not getting well*	2	3	0.71 (0.64 – 0.78)	0.74 (0.67 – 0.8)

25. I shall stop doing advised tests when I am feeling well*	1	1	0.7 (0.62 – 0.77)	0.65 (0.57 – 0.73)
26. Taking medication as per schedule is troublesome for me*	3	3	0.73 (0.67 – 0.8)	0.67 (0.6 – 0.75)

* items' coding were reversed, since negatively (reversely) framed items.

a*. values could not be computed as iterations assuming ordinal level did not converge.*

TABLE 3 – Relatedness (η^2 value) of the individual items to the dimensions retained.

Items in the tool	intensiveness (Dimension 1)	communication (Dimension 2)	intensiveness (Dimension 3)	Compliance (Dimension 4)	System (Dimension 5)	set-up (Dimension 6)
1. The Doctor(s) behave with me as per my expectations	0.18408	**0.52337**	0.29020	0.07080	0.26206	0.10903
2. The behavior of the support stuff(s) is as per my expectations	0.17484	**0.19143**	0.09625	0.03720	0.15269	0.02041
3. The Doctor(s) listen thoroughly to my complaint(s)	0.33095	**0.47984**	0.08914	0.08088	0.04631	0.17919
4. The Doctor(s) examine me as per my expectations	0.07582	**0.33210**	0.07652	0.33074	0.15243	0.09719
5. I feel hassled when referred to another room/facility from this OPD*	0.02006	0.06019	0.21652	0.18975	0.13147	**0.04924**
6. The cleanliness and basic facilities (e.g. water, waiting area etc.) at OPD are up to the mark	0.00180	0.06941	0.18622	0.16310	0.07585	**0.48332**
7. It is time-intensive to attend OPD*	**0.39512**	0.12680	0.01447	0.29531	0.23592	0.09953
8. The waiting time before OPD is much more than my expectation*	**0.26845**	0.13304	0.03684	0.09589	0.33255	0.16997
9. The waiting time for getting the medicines from pharmacy is as per my expectations	**0.43062**	0.12623	0.09375	0.10810	0.10318	0.12686

10. I feel exhausted when I come to visit OPD*	0.27290	0.34395	0.08628	0.09693	0.02059	**0.26608**
11. I feel treatment at OPD is costly for me (direct and indirect costs)*	0.01591	0.02716	**0.22047**	0.01135	0.04722	0.04953
12. It is difficult for me to afford the cost of medicines, that are not available free	0.13447	0.04177	**0.32806**	0.18634	0.20072	0.13586
13. It is difficult for me to afford the cost of different tests that I have to get done from outside*	0.21533	0.01830	**0.18608**	0.00804	0.18059	0.08140
14. I tell others to attend OPD for their illnesses, that I feel cannot be handled at the local level	0.29143	0.27218	0.19603	0.06511	**0.08724**	0.19346
15. I am confident that relief is obvious when I visit the OPD	0.00309	0.24230	0.20623	0.00265	**0.08582**	0.03800
16. I feel cure is imminent when I visit the OPD	0.12802	0.05574	0.18964	0.27106	**0.12165**	0.16599
17. I don't understand the directions given by the doctor including the schedule to take medications*	0.33303	**0.26719**	0.29112	0.12437	0.08591	0.04857
18. I shall report to my doctor as early as possible when my condition deteriorates	0.13394	0.14822	0.07853	0.28919	**0.11293**	0.07052
19. I shall do prescribed test(s) at the earliest	0.01796	0.22031	0.14681	0.02552	**0.18606**	0.08273
20. I shall visit the Doctor on the dates I'm called for follow up	0.25049	0.12925	0.17903	0.08557	**0.31412**	0.04362
21. I shall stop following the life style modification advises when feeling well*	0.03856	0.19052	0.12274	**0.05884**	0.02744	0.00150
22. I shall cut down the dosage of my medication on my own*	0.39298	0.23893	0.08545	**0.15340**	0.00301	0.01379
23. I shall stop taking my medication when I am feeling well*	0.26449	0.32903	0.17746	**0.10150**	0.00307	0.02879

24. I shall stop following Doctor(s)' advice if I'm not getting well*	0.17115	0.19598	0.19681	**0.21389**	0.02775	0.00676
25. I shall stop doing advised tests when I am feeling well*	0.43402	0.02605	0.10982	**0.11632**	0.01721	0.25129
26. Taking medication as per schedule is troublesome for me*	0.00072	0.00337	0.16340	**0.13134**	0.02976	0.12960

* items' coding were reversed, since negatively (reversely) framed items.

4. Conclusion

The study concluded with the fact that the new tool had good internal consistency and construct validity with ordinal level of responses of the items. Considering the dimensions in the MCA solution a good proportion (percentage) of variability in the ordinal scale response was accounted for with the first six dimensions, since a linear principal component method was considered conceptually incorrect. The η^2 values of the items spread over the dimensions provided evidence of inter-dependence of the dimensions.

Since MCA was used as a principal component method and not as a descriptive tool for individual response, factor map for individual respondents were not reported. Another approach can be considered in future to study the individual response in terms of the items and their difficulty by means of item response theory.

The participants in our study mainly had the diagnoses of Hypertension and Diabetes as the patients with other two major NCDs generally go to the respective speciality OPD held daily. Therefore with a better resource the tool can be further attempted to validate among the patients from other OPDs in the hospital and also in a multi-centric mode. Issue of sample size was an area where the current study was at a lower end. However a multi-centric multi-OPD based study will not only give the means to access

further diversity among respondents but a rational increase in sample size will also be possible resulting in a more accurate (more explained variability) assertion.

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