VALIDATION OF SCORE CARD TO PREDICT ADHERENCE OF MEDICATIONS IN CHILDREN AND ADOLESCENT POPULATION WITH PSYCHIATRIC DISORDERS

Dissertation submitted to the Tamil Nadu Dr.M.G.R Medical University

in partial fulfillment of the Degree of MD in Psychiatry

Final Examination, April 2016

CERTIFICATE

I hereby declare that this dissertation titled "Validation of Score Card to Predict Adherence of Medications in Children and Adolescent Population with Psychiatric Disorders" is a bonafide work done by Dr. Sony Mathews Lukose at the Department of Psychiatry, Christian Medical College. This work has not been submitted to any University in part or full.

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CERTIFICATE

I hereby declare that this dissertation titled "Validation of Score Card to Predict Adherence of Medications in Children and Adolescent Population with Psychiatric Disorders" is a bonafide work done by Dr.Sony Mathews Lukose under my guidance at the Department of Psychiatry, Christian Medical College. This work has not been submitted to any University in part or full.

Dr. Paul Swamidhas Sudhakar Russell
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D E C L A R A T I ON

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January 21, 2015

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Sub: **Fluid Research Grant Project:**
Medication non-adherence in children and adolescents with psychiatric disorders: predictive accuracy, validity and reliability of a newly developed score card.
Dr. Sony Mathews Lukose, PG Registrar, Psychiatry, Dr. Paul S. S. Russell, Dr. Minju K. A, Dr. Shonima A. V, Child and Adolescent Psychiatry unit, CMC, Vellore.

Ref: IRB Min No: 9193 [DIAGNOSE] dated 08.12.2014

Dear Dr. Sony Mathews Lukose,

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1. Institutional Review Board approval 2. Agreement

Could you please sign the agreement and send it to Dr. Nihal Thomas, Addl. Vice Principal (Research), so that the grant money can be released.

With best wishes,

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Dear Dr. Sony Mathews Lukose,

The Institutional Review Board (Blue, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project entitled "Medication non-adherence in children and adolescents with psychiatric disorders: predictive accuracy, validity and reliability of a newly developed score card." on December 08th 2014.

The Committees reviewed the following documents:

1. IRB Application format
2. Curriculum Vitae' of Drs. Sony Mathews Lukose, Paul S. S. Russell, Minju K. A, Shonima A. V
3. Informed Consent form (English &Tamil)
4. Information Sheet (English &Tamil)
5. Proforma
6. No of documents 1-5

The following Institutional Review Board (Blue, Research & Ethics Committee) members were present at the meeting held on December 08th 2014 in the CREST/SACN Conference Room, Christian Medical College, Bagayam, Vellore 632002.

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We approve the project to be conducted as presented.

The Institutional Ethics Committee expects to be informed about the progress of the project, any **adverse events** occurring in the course of the project, any **amendments in the protocol and the patient information / informed consent**. On completion of the study you are expected to submit a copy of the **final report**. Respective forms can be downloaded from the following link: http://172.16.11.136/Research/IRB_Polices.html in the CMC Intranet and in the CMC website link address: http://www.cmch-vellore.edu/static/research/Index.html.

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Fluid Grant Allocation:

A sum of 5,000/- INR (Rupees Five Thousand only) will be granted for 6 months.

Yours sincerely,

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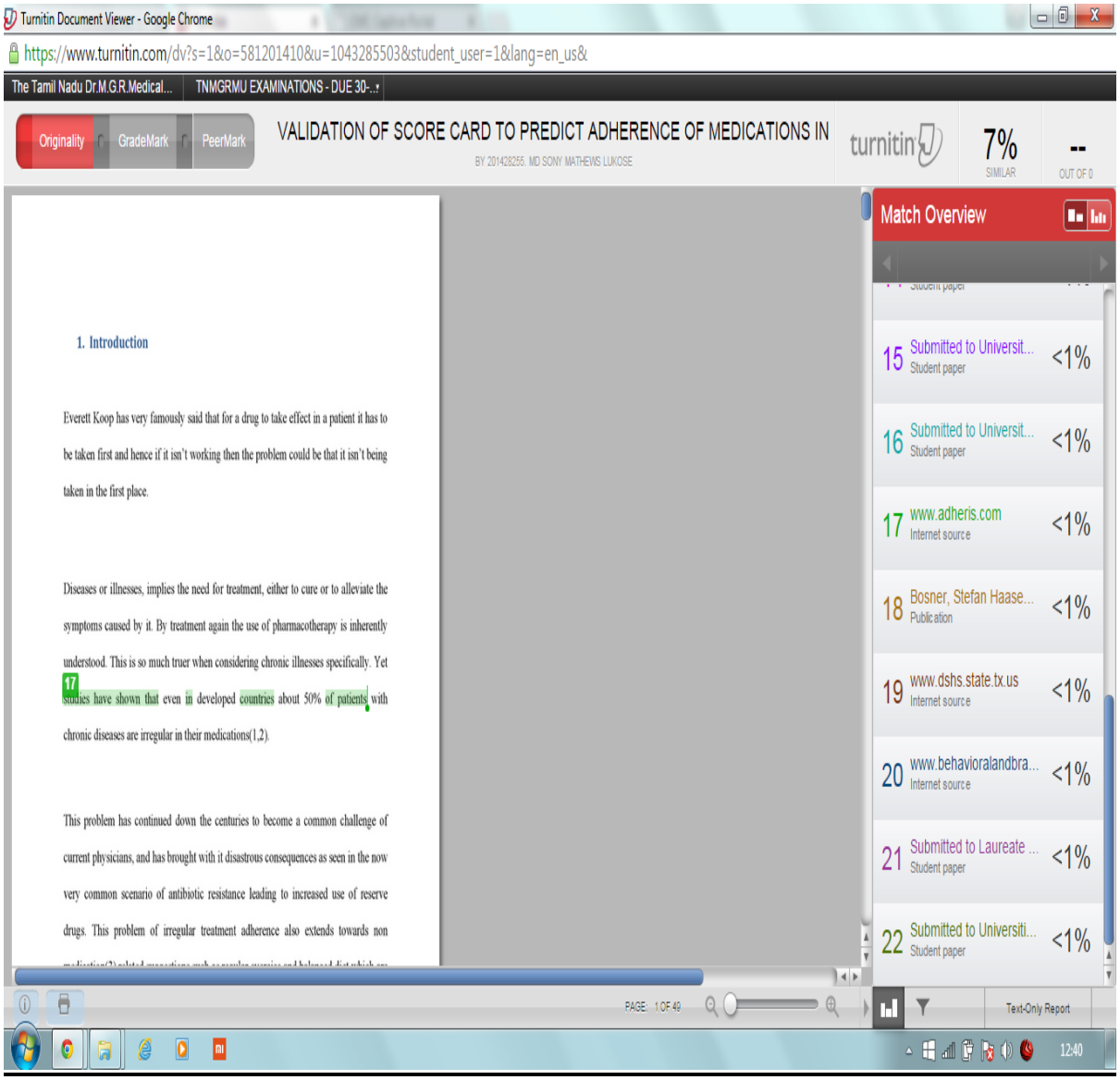
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1. Introduction
Everett Koop has very famously said that for a drug to take effect in a patient it has to be taken first and hence if it isn't working then the problem could be that it isn't being taken in the first place.
Diseases or illnesses, implies the need for treatment, either to cure or to alleviate the symptoms caused by it. By treatment again the use of pharmacotherapy is inherently understood. This is so much truer when considering chronic illnesses specifically. Yet studies have shown that even in developed countries about 50% of patients with chronic diseases are irregular in their medications(1,2).
This problem has continued down the centuries to become a common challenge of current physicians, and has brought with it disastrous consequences as seen in the now very common scenario of antibiotic resistance leading to increased use of reserve drugs. This problem of irregular treatment adherence also extends towards non
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And with much importance, to my dear little patients and their kind-hearted caregivers who in the midst of their suffering consented to participate in a study to add to the knowledge of the world to help others.

Table of Contents

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Everett Koop has very famously said that for a drug to take effect in a patient it has to be taken first and hence if it isn't working then the problem could be that it isn't being taken in the first place.

Diseases or illnesses, implies the need for treatment, either to cure or to alleviate the symptoms caused by it. By treatment again the use of pharmacotherapy is inherently understood. This is so much truer when considering chronic illnesses specifically. Yet studies have shown that even in developed countries about 50% of patients with chronic diseases are irregular in their medications(1,2).

This problem has continued down the centuries to become a common challenge of current physicians, and has brought with it disastrous consequences as seen in the now very common scenario of antibiotic resistance leading to increased use of reserve drugs. This problem of irregular treatment adherence also extends towards non medication(3) related suggestions such as regular exercise and balanced diet which are equally important in establishing good health amongst patients.

In our current century where technological advances have brought about changes in treatment that was unimaginable just a few decades ago, medication adherence

becomes a serious threat to the quality healthcare outcome. And it is not just the patient who suffers by this. The burden is also borne by the relatives or caregivers of the patient and the society at large by the economic and social burdens imposed inadvertently. Every year about hundreds of billions of dollars are spent for the consequences of medication non adherence (4). But that has not been able to stem this crisis. And importantly it is money that can be diverted to other important needs or requirements, especially so in countries with poor financial resources.

And so it becomes of paramount significance that research be focussed not just on seeking newer modes of treating patients, but also on identifying this major problem of medication non adherence. And better so if before the problem has arisen rather than identifying it after it has happened.

2. Review of Literature

2.1 History

Drug non adherence is a challenge that has been faced by physicians since the ancient days and has been observed as early back as in the times of Hippocrates when he had mentioned in his writings that it was essential to carefully watch on a certain problem with patients where they would commonly lie about complying with what was prescribed to them. And it was this particular behaviour according to Hippocrates that would lead to unfortunate events such as death which could not be justified even if the prescribed medication was difficult to take or bitter.

In the past century so much progress has been made in medical science. However despite all that, adherence to medications in chronic diseases is still a factor that limits the outcome. In chronic diseases the need for complex regimen or the presence of severe adverse effects only compounds the problem(5). Non adherence also presents itself as a source of bias in clinical research(6). An adherence averaging 50% would in a clinical trial increase the require sample size by fivefold as against 100% adherence(7).

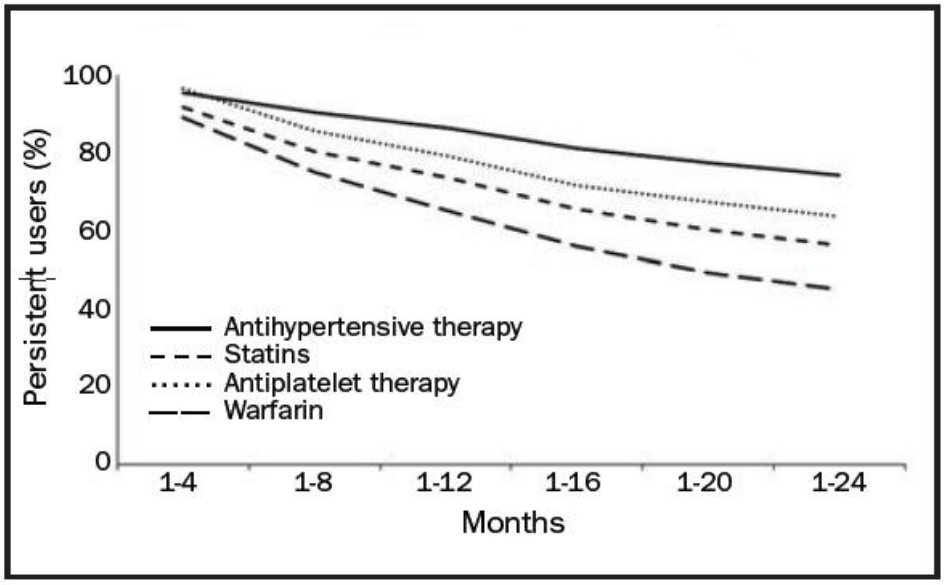


Figure 1: Persistence with secondary prevention medication in the 24 months after ischemic stroke in Sweden. Persistent use of secondary preventive drugs declines rapidly during the first 2 years after stroke (8).

As a result several studies have looked into the issue of non-adherence in the past few decades. The enormous number of studies done, however are of varying methodologies and hence unclear at times(9). Different nomenclatures for the problem have been used such as compliance, adherence and concordance. The definitions or implied meaning for these terms are varied(10) and at times even not defined by people undertaking research in the issue(11). Also the use of words such as compliance brings with it a negative connotation due to the expected submissiveness of the patient to the doctor's commands (6). Hence the term adherence would be more appropriately used in this context.

As difficult as it can be in medical illnesses, the problem of non-adherence appears more challenging in the treatment of psychiatric disorders due to various factors which includes illness variables and social factors at the least(12). The impact of this is a decrease in the quality of life as well as an added burden over the health care system(12). Hence the need to stem this crisis is the need of the hour.

2.2 Definition

The World Health Organization defines therapeutic adherence as "the extent to which a person's behaviour – taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider."(2)

Compliance is a word that has been used consistently in this context. Compliance is defined as 'The extent to which the patient's behaviour matches the prescriber's recommendations' (Haynes, Taylor and Sackett, 1979). However as mentioned earlier it does bring a negative aspect towards the therapeutic relationship(9). Due to this aspect, the inability of a patient to follow the prescribed suggestion would lead the patient's behaviour to be interpreted as deviant.

Adherence is another word that has been used with the same intention(10). It brings about a change with the patient also being considered free to decide whether he needs to follow the instruction his doctor has provided. And hence modifies the definition as,

‘The extent to which the patient’s behaviour matches agreed recommendations from the prescriber.’(11)

Concordance is a newer term that is being used in relation to medication taking. It was originally defined as “a new approach to the prescribing and taking of medicines. It is an agreement reached after negotiation between a patient and a health care professional that respects the beliefs and wishes of the patient in determining whether, when and how medicines are to be taken(13). Although reciprocal, this is an alliance in which the health care professionals recognise the primacy of the patient’s decisions about taking the recommended medications” (Medicines Partnership, 2001). This was brought up with the conceptualisation thatboth the patient as well as the prescriber had a part to play in the process of taking medications (Horne, 1993; McGavock, 1996).

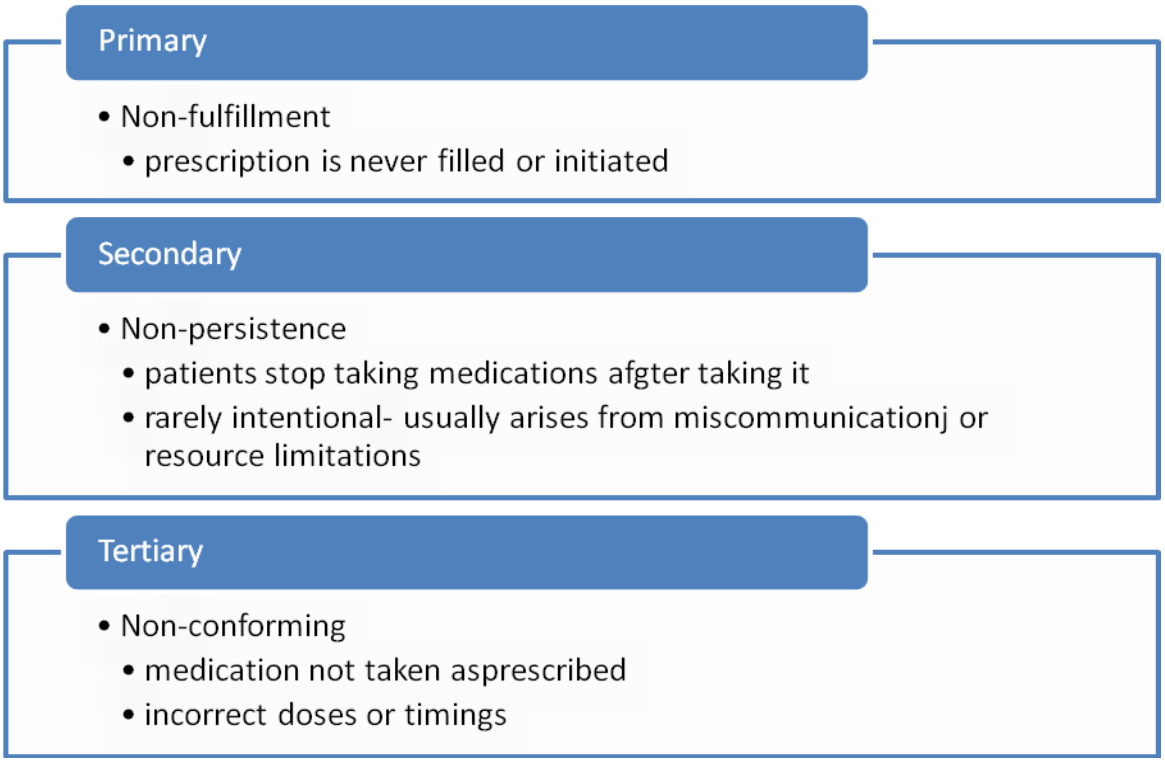
However as simple as these may sound, these slight changes of words do bring about a significant change. Even the term concordance used is not a word meant to substitute the two earlier terms but is rather a process described to change the dynamics in the patient physician relationship to more of an equal. But it still does not measure the end point of patient behaviour of taking medicines.

In this context it can be also argued that non adherence need not be entirely harmful and in some cases may be useful if the prescription was a bad one. This becomes clearer in the light of prescriptions being considered as a ‘therapeutic experiment’

(Sackett, 1985). Hence the fallible nature of the physician is addressed as well highlighting that the physician is also equally responsible for the instructions to be followed.

2.3 Types of Non Adherence

Non adherence can be of different types. The first is patients who do not have the initial prescription dispensed. The next are who do not present regularly for having continued medications. The third lot can be those who do have their medications dispensed but do not take them at the dosages that may have been advised.



As the above figure indicates these three types of non-adherence can be classified into primary, secondary and tertiary. They may also be called as non-fulfilment, non-persistence and non-conforming respectively.

The impact of non-adherence also varies in clinical scenarios under which a particular drug is prescribed wherein certain situations like in the use of oral contraceptives, even a single missed dose could change the outcome significantly as against a person with dyslipidemia missing his cholesterol lowering drug(12). Also longer acting drugs allow a certain deviation in dosing in comparison to a shorter acting drug. This concept is understood better in terms of drug forgiveness, which is arrived at by subtracting the dosing interval from the duration of action(14).

The figure below illustrates the approximate percentages of various consequences after a prescription has been filled in. Of 100 prescriptions filled only about 50-70 actually go to a pharmacy. And only 25-30 actually take them properly while only 15-20 refill them as prescribed (14). That points out to a huge problem in the system despite various measures being implemented by organisations world over to address this issue.

Figure 3: Gap between prescription and medication use.(14)

2.4 Prevalence

2.4.1 Psychiatric illnesses in children and adolescents outside India

The prevalence of any ICD-10 diagnosis among a random sample of 5-10 year old children in Bangladesh were found to be at 15% with an increased rate of obsessive compulsive disorders as well as increased prevalence of behavioural problems among slum children (15). This study concluded that based on these figures about 5 million children by virtue of extrapolation have psychiatric disorders and in a country with

very few child psychiatrists there would be a significant gap between what was needed and what was available.

2.4.2 Non adherence in Medical illnesses outside India

As mentioned previously WHO estimates that about 50% of patients with chronic diseases are irregular with their medications(2). In fact a recent article mentioned that the problem of non-adherence costs Americans between 100-280 billion US dollars annually(16). Similarly the problem of non-adherence amongst Europeans has been estimated to cost the EU about 1.25 billion Euros annually(17).

In a study conducted in Nigeria about 41% of the participants reported themselves to be non-compliant with their anti hypertensives(18). Another study in Ireland showed about 18% to be consistently non adherent to medications prescribed(19).

2.4.3Non adherence to medications in Psychiatric illnesses outside India

Ghaziuddin et al (20), in a study conducted to assess the prevalence as well as predictors of non-compliance in adolescents with psychiatric disorders found that 33.8% were non adherent. They also concluded that it was a relatively common problem and a difficult one to predict.

In a study by Pogge et al conducted in the U.S, among 86 adolescent psychiatric inpatients, following discharge at 10 months only about 45% were adherent to the prescribed medications(21). Another study conducted in Brazil, which focussed on victimized children, those children who had mood disorders alone were found to have higher rate of adherence of 79.5%. Those with substance abuse disorders alone had poorer compliance at 40%. An intermediate rate of 50% was observed among those having both disorders(22).

2.4.4 Psychiatric illnesses in child and adolescent population in India

Generally data on mental needs of children in India are limited(23). The Indian Council of Medical Research conducted an epidemiological study to study the prevalence rates of psychiatric disorders in child and adolescent population. This was conducted in two centres, namely Bangalore and Lucknow. At Bangalore about 2064 children aged less than 16 years were studied which showed a prevalence rate of psychiatric disorders in child and adolescent population to be at 12.5%(23).

In another study conducted at Chandigarh involving school children aged between 4-11 years, about 6.33% were found to have an ICD-10 criteria based psychiatric disorder when assessed by a psychiatrist after initial screening by parents and teachers.

Estimates by teachers of the prevalence rates were higher at 10.17% as compared to estimates of parent's at 7.48%(24).

A follow up study to the Chandigarh study which looked at the incidence of psychiatric disorders in children revealed an incidence of 18 per 1000. However the authors also suggested that the higher dropout rate in the study could have resulted in a lower than expected results(25).

2.4.5Non adherence in Medical illnesses in India

Adherence to anti TB medications in developing countries has been reported at 40%(26). In a cross sectional study conducted in Mumbai about 84% of patients were adherent to the DOTS scheme(26). In another study conducted among diabetics in Dehradun only 16.6% were adherent to the prescribed medications while only 23.3% were adherent to the prescribed dietary restrictions(27).

According to the APA, about 50% of children with chronic medical conditions are found to be non-adherent with their prescribed treatment(28). Studies done have revealed that non adherence among children with chronic medical conditions have resulted in increased health care use(29).

2.4.6 Non adherence in psychiatric patients in India

Among psychiatric patients about 50% and 75% are non-adherent by the end of the first and second year respectively(30). In a study conducted among schizophrenia patients followed up at a centre in Chennai, about 58% reported non-compliance at some point of their treatment course(31). 31% of schizophrenia patients who attended a walk in clinic in India did not follow through for further detailed evaluations while another 32% would not turn up for follow-ups after the detailed evaluation (32).

Also about 10-60% of patients on treatment for depression were likely to discontinue their medications(33). Whereas among those patients on treatment with mood stabilisers, between 18-52% were non adherent(34). In comparison to non-depressed patients, depressed patients were found to be 3 times more likely to become non adherent to their medications(35).

Other Indian studies looking into prevalence of non-adherence give widely varying results. In a study which looked into people with mental disorders, 50% of whom were suffering from schizophrenia, non-adherence was observed in about 38% of those studied(36).

In a study conducted at a tertiary care hospital in Kolkata, nearly 67% of 239 unipolar depressive patients were non adherent with their medications(37). This led them to relatively requiring more medications in comparison to those patients who were adherent to their prescribed treatment.

In another tertiary care centre in Chennai, a study done over 8 months among 200 out patients diagnosed with a psychiatric illness by a psychiatrist revealed that more than 80% of the assessed patients were non adherent with their medications(38).

In a cross sectional study done at IMHANS (Institute of Mental Health and Neurosciences) in Srinagar, only 26% of 200 patients were non adherent. The study was done from 2011 to 2012 with a newly designed questionnaire among out patients, while excluding new patients.

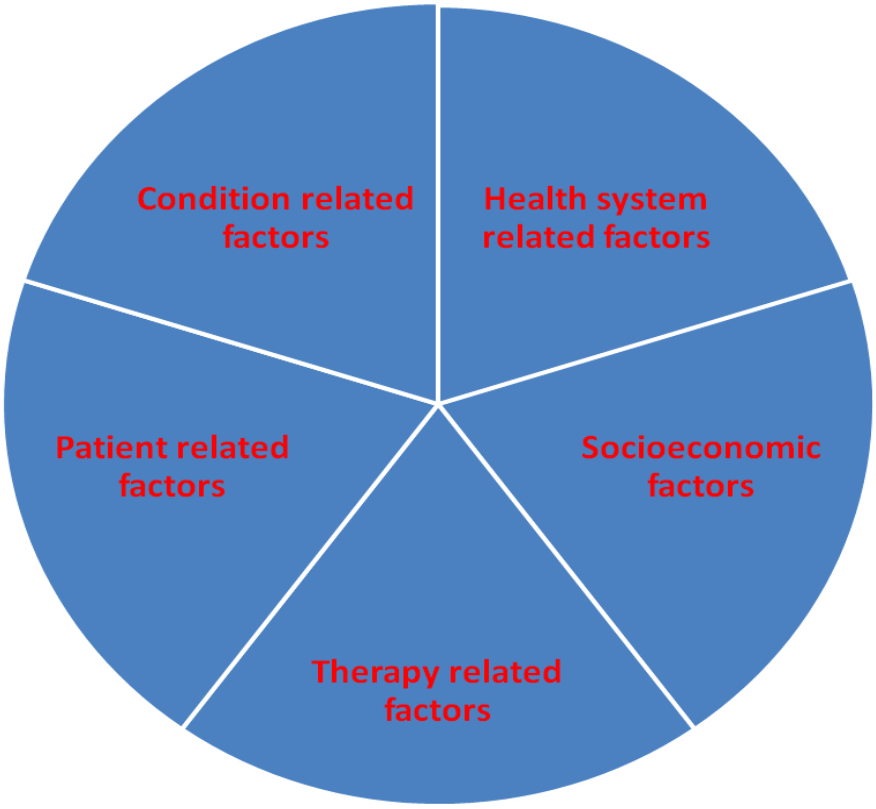
2.4.7 Non adherence in children and adolescent psychiatric population in India

The problem of medication non adherence is equally present in paediatric populations(39). A study by Costello et al have suggested that in comparison to adults, it may be worse in children and especially so in adolescents(40). This occurred across all conditions and required significant efforts from caregivers to balance concerns of medications versus the concerns of the illness(41)

Overall there was a paucity of data studying adherence of medications among children with psychiatric disorders in India. In a study by Sitholey et al conducted at Lucknow, among 24 children newly diagnosed with ADHD, 83.3% were non adherent within a month(42).

2.5 Factors

According to the WHO factors related to non-adherence fall mainly under 5 domains. These are patient related, condition related, therapy related, health system related and socioeconomic factors(2).



Understanding this model helps in directing specific solutions under those specific factors in a more focussed manner. It is easier for the physician to elicit or clarify for reasons if medication non adherence is suspected for the poorer outcome than expected.

Patient- related factors are those which occur due to a reduced understanding of the disease as well as its complications. Therapy related factors are chiefly related to the failure by the treating doctor to recognize noncompliance and prescription of complex drug regimens. Any solution to improve adherence can be considered only when all of these factors are taken into consideration.

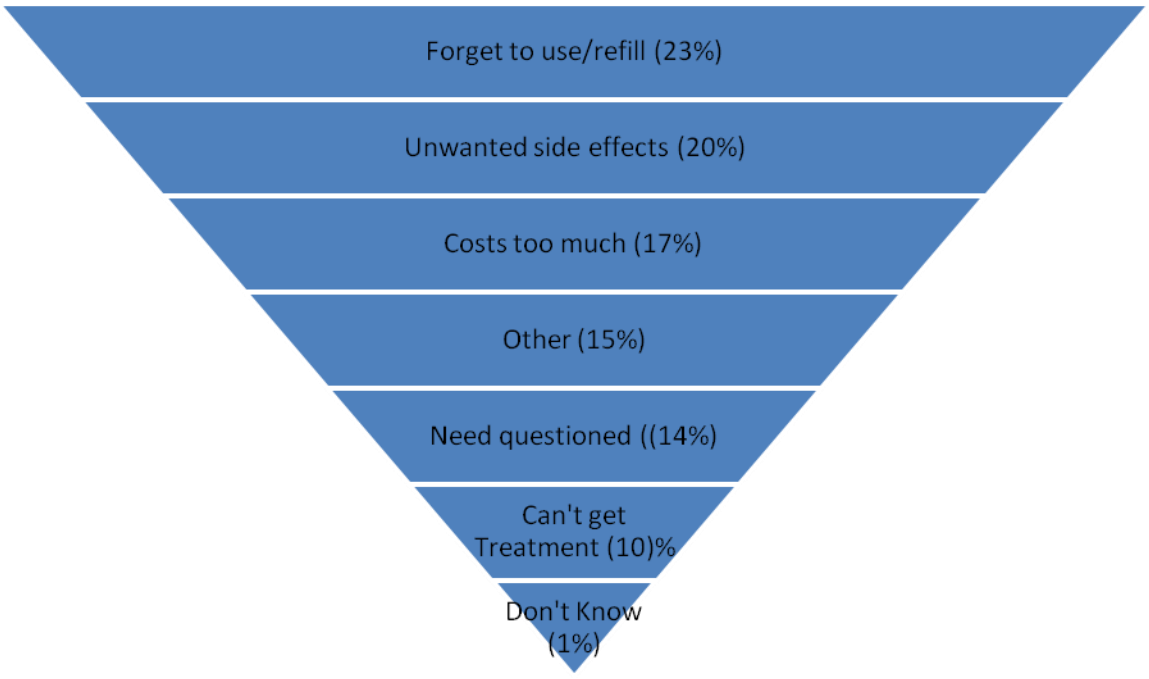


Figure : Reasons cited for medication Non adherence (43)

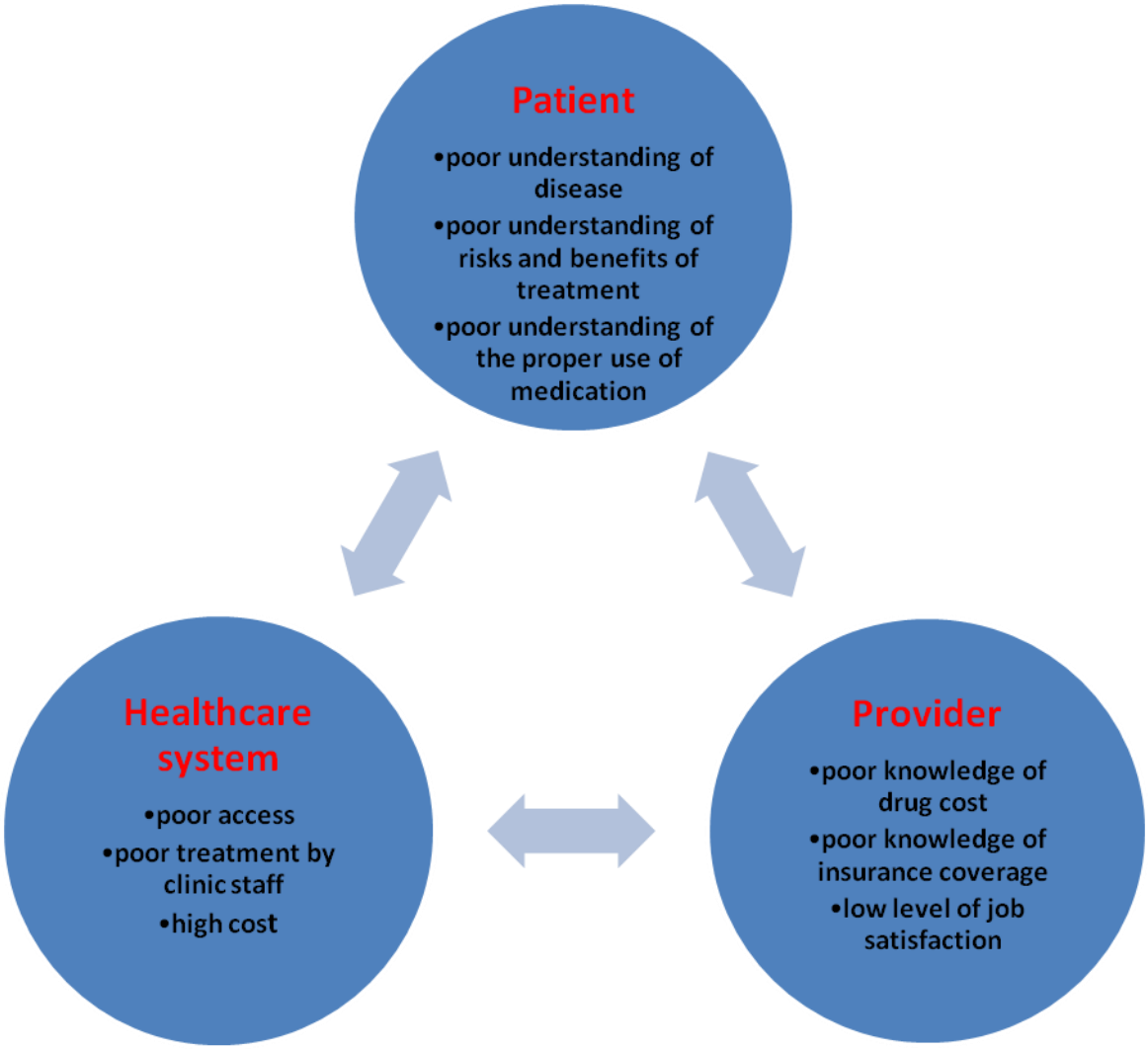


Figure : Issues related to provider-patient communication, physician interaction with the health care system and patient interaction with the health care system (44)

We will now look at a few factors that have an impact on medication adherence keeping in mind the score card that is being validated in this study.

2.5.1 Gender

Gender is a factor that can have a bearing on the adherence pattern towards medications. This is especially more so if the said condition is for a behavioural disorder (45). In a study conducted in the United States among 29.5 million adults, it was found that women were more likely to adhere to their medications (46).

2.5.2 Education

Education is a factor that has been looked into and found to be associated with medication adherence behaviours. In a study conducted in Pakistan among diabetic patients, it was found that maternal education had a significant relationship with medication adherence (47). However the direction of this significance was not clearly stated. A similar finding was echoed in a study done in Tanzania, again among diabetic patients (48). In this study it was observed that educational status of the care giver had association with medication adherence.

In yet another study conducted in south west Nigeria it was observed that primary school education was associated with higher self-reported compliance in patients being

treated for hypertension(18). A study in Finnish adolescents with epilepsy showed that good parental support had a positive effect on medication adherence (49). This could possibly be associated with the parental education though not specified so.

However there are studies that show an opposite trend also with people of lower educational status showing better compliance(50). In a review article published in 2008, it was found that the effect of educational status on medication adherence being equivocal (51).

2.5.3 Socio Economic Status

Treatment implies a cost that has to be borne by the patient for a period ranging from a few days to lifelong. Studies have found that this cost can be a reason for many to poorly adhere to their medications (52). Especially so in case of patients with chronic diseases, cost of treatment can be a burden if their income is inadequate or they have nil or low insurance support to meet their needs (53).

In a study conducted among hypertensive patients it was found that between 30-46% of patients were poorly adherent to their prescribed medications. The survey was conducted by chart reviews as well as telephonic interviews. It was noted that employment and cost were factors that were associated with non-adherence(54).

Dutta et al in their study looking at socio-demographic factors for non-compliance to treatment, in patients with locally advanced cervical cancer being treated at a rural medical college in West Bengal, found not surprisingly that poor socio economic status was the second most common factor for non-compliance(55).

In another study conducted among patients with affective disorders who were prescribed Lithium carbonate, poor adherence was associated with patient's perceptions of the cost involved. This study considered adherence to be defined by serum lithium level within a recommended therapeutic range and attendance for a period of six months prior to the study at 75 per cent or more of regularly scheduled clinic appointments (52).

Also about 10% of patients reported costs as a reason for non-compliance towards inhalers in patients with bronchial asthma. This was in a study conducted at 2 medical colleges in Karnataka in the respective department of respiratory medicine following up patients over a 2 year period (56).

2.5.4 Type of Illness

The duration of the illness remains another crucial factor related to medication adherence. Acute illnesses are known to have a better adherence than with chronic illnesses (57). In a study among tuberculosis patients, it was noted that while

comparing the adherence rates of different durations of treatment of 3, 6 and 12 months, adherence rates were higher for shorter durations at 87%, 78% and 68% for the three regimens, respectively (57).

However certain other studies such as by Sharkness et al showed that over the years the adherence rate improved due to probable improvement of patients denial and a better understanding of the illness and need for treatment (58).

2.5.5 Nature of Illness

Sultan et al in their recently conducted study in 2013 in a medical college in Andhra Pradesh, amongst out patients over a period of 7 months, concluded that the presence of continuous illness like schizophrenia resulted in an increased rate of non-adherence(59). About 45% of patients with schizophrenia in their study were non adherent to their prescribed medications. The reason attributed for this was a lack of understanding of the illness.

A similar finding was echoed by Pareek et al who in their study concluded that the presence of a chronic illness requiring long term treatment was cited by caregivers of patients as a reason for the problem of non-adherence(60).

2.6 Measuring Non Adherence

There are several ways to assess medication non adherence (61). These would include both subjective as well as objective measures. Subjective measures used would include eliciting history from the patient as well as the caretaker, checking patient's case note recordings, looking into prescription dispensing, as well as the treating physicians own assessment of the patients medication taking behaviour.

Among these the patient self-report is reported to be most accurate (63) and was also seen to be comparable to of another study assessing medication non adherence in mood disorders (33). In a study conducted in Canada it was found that physicians were unable to predict the medication behaviour in more than 70% of their patients despite having known them for several years (64).

Adherence can also be measured by collateral information gathered from family members, pharmacists as well as by methods such as pill counting and estimation of drug levels in the blood. We shall look into the challenges of these methods in the following paragraphs.

Though self-reporting has been found to be a good method of assessing medication non adherence (65), asking patients for their drug taking history can be beset with

problems where the patients can claim to be on regular medications which would however be countered by alternate methods used to confirm such as counting of pills as was seen in the study done among a group of patients with affective disorders (33). There could be both decreased as well as increased doses being taken.

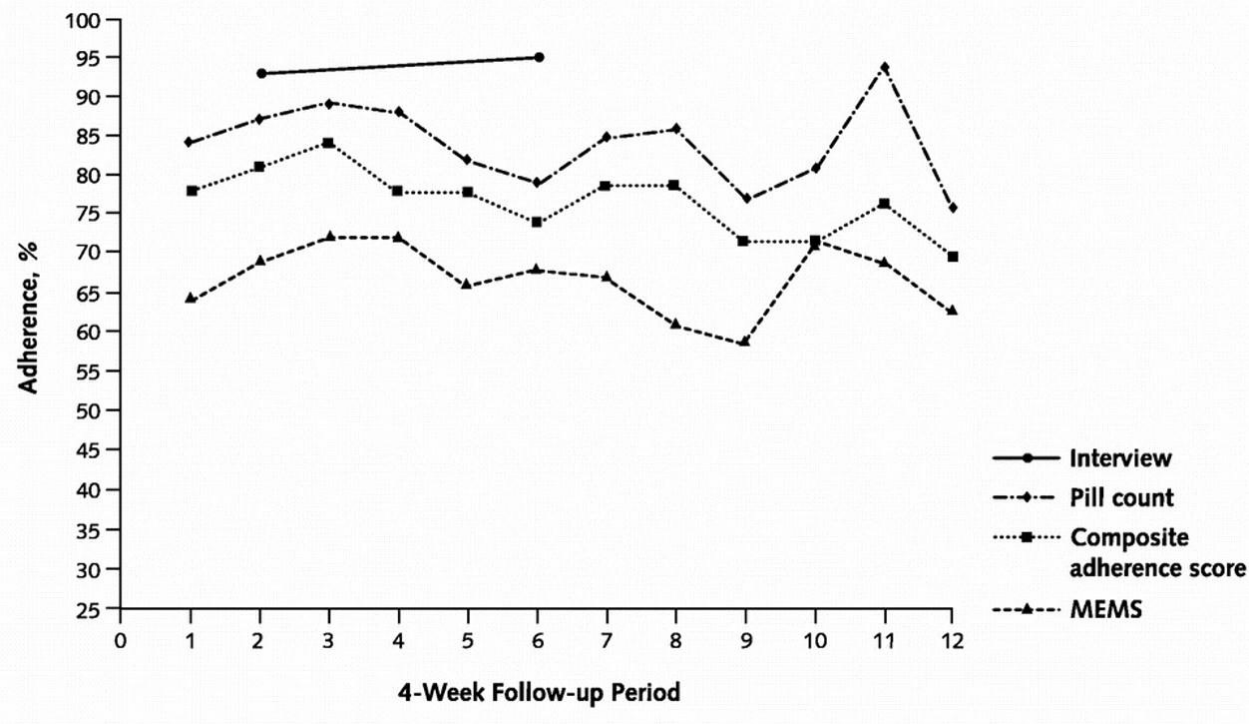


Figure: Comparison of varying adherence rates by using different methods in the same patient (66)

This study (67) looked into the various adherence rates obtained using various methods. They came to a conclusion that adherence may be better represented by a composite score while it was underestimated by using MEMS (medication event monitoring system) and overestimated by direct interview and pill counts.

The problem of inaccuracy in self-reporting may occur due to patients facing the challenge of being honest with their treating physicians of their drug taking behaviour and thereby causing them displeasure or being embarrassed (66). Or in other cases could be due to plain unawareness.

Though the help of the family members may be roped in dealing with the problem of non-adherence, it is physically impossible to do so all the time. There could also be the physician increasing the risk of strained relations between the patients and their family members.

Counting of pills is the other method that can be used. But again there can be instances when pill numbers may tally with the patient secretly discarding the medications to avoid getting caught. Or it may also occur that the patient may not be taking doses in the manner prescribed(68).

Biochemical evidence of medications(69) being adhered to, through assessing the blood or urine, though reliable may not be cost effective on a regular basis as well as again damages the therapeutic relationship between the patient and the treating physician. Also it may not reflect whether the accurate dosing is being taken or even prescribed and may just say whether the drug was taken or not. There may also be

drugs which cannot be estimated by such methods or even individual variations of absorption and/or metabolism of drugs in patients especially so in extremes of ages.

All of this suggests that there is not a single way by which medication non adherence can be surely identified. And it would be rather a combination of methods that would serve to identify the problem.

For certain patients the taking of medications would be a stark reminder of the fact that they have an illness. Hence denial would be a reason for such people to be non-adherent to their medications (70,71).

A physician who is perceived to be rigid and cold in his dealings may not go well with patients who expect a friendlier and warm person to help them with their medical problem. And this could also cause difficulty in maintain adherence to medications.

Even simple measures improving patients satisfaction with the care provided such as reducing the waiting period for or understanding and responding according to the patients cultural values is found to influence medication adherence positively (72)

And so the challenge to researchers has been as to how to measure adherence to medications has remained (73). And the lack of a valid method to measure non adherence itself has been a stumbling block in medication adherence research.

Direct methods of measuring medication adherence are considered to be the most representative of truth. However to many patients this would be unacceptable being invasive. Besides this may be feasible in situations of a single dosing, intermittent medications or in hospitalised patients (73).

With the advent of microprocessors and the use of electronic devices, or MEMS (medication event monitoring system), which enables both frequency and time of opening of the medication bottle to be measured (73), there have been startling discoveries of ‘drug holidays’ and ‘white coat adherence’. This was when the patient would become compliant towards the time of the consultation time (67).

Though methods such as electronic monitoring may be used to enhance adherence, if a patient did not intend to be adherent then he/she would not make the effort to use an electronic dispenser in an expected manner(74).

Now we will look into various measures used to assess medication non adherence.

2.6.1 Morisky Medication Adherence Scale – 8

The original Morisky scale was a 4 item scale that was a self-reporting questionnaire with dichotomous answering (75). It was developed in 1986 and validated in a setting of patients on antihypertensive medications. It was based on the premises of drug errors which could occur in 4 different ways. It could be due to the patient simply forgetting or maybe due to a carelessness regarding adhering to prescribed schedule or stopping and starting the drug when based on feeling better or worse(76). It had a sensitivity of 81% and specificity of 44%.

MMAS-4	MMAS-8
1) Do you ever forget to take your medicine?	1) Do you sometimes forget to take your pills?
2) Are you careless at times about taking your medicine?	2) People sometimes miss taking their medications for reasons other than forgetting. Thinking over the past two weeks, were there any days when you did not take your medicine?
3) Sometimes if you feel worse when you take the medicine, do you stop taking it?	3) Have you ever cut back or stopped taking your medicine without telling your doctor because you felt worse when you took it?
	4) When you travel or leave home, do you sometimes forget to bring along your medicine?
	5) Did you take all your medicine yesterday?
4) When you feel better do you sometimes stop taking your medicine?	6) When you feel like your symptoms are under control, do you sometimes stop taking your medicine?
	7) Taking medicine every day is a real inconvenience for some people. Do you ever feel hassled about sticking to your treatment plan?
	8) How often do you have difficulty remembering to take all your medicine? ___A. Never/rarely ___B. Once in a while ___C. Sometimes ___D. Usually ___E. All the time

Table: Comparison of MMAS-4 and MMAS-8

In 2008 it was further modified into an 8 item questionnaire with the first 7 questions maintaining the dichotomous pattern, while the eighth and final question was a 5 point likert type question. This improved the sensitivity to 93% and the specificity to 53%. This is now a widely used tool for assessing medication non adherence.

Adherence	MMAS-4 Score	MMAS-8 Score
High Adherence	0	0
Medium Adherence	1-2	1-2
Low Adherence	3-4	3-8

Table: Scoring ranges for MMAS-4 and MMAS-8

The researchers, who developed the MMAS-8 while working among hypertensive patients, proposed that the tool was a very simple one to use in practical situations like an outpatient setting and was therefore a relevant tool to aid in identifying patients with medication non adherence (77).

The qualities that make it a preferred tool include it's validation into several languages across the world, it's use in different settings and diseases (75). In a study conducted in Brazil among hypertensive patients it was found that the MMAS-8 translated into Portuguese was a valid tool to help in identifying medication non adherence and there was a significant relationship between MMAS-8 scores and Blood Pressure control (78).

However the MMAS-8 is not a comprehensive measure and only captures non adherence in certain areas (77). It also is unable to predict or assess reasons towards non adherence. And so by this lacking makes it less useful in applying interventions to address such factors.

Another drawback is that it is only able to measure adherence to medications in one particular disease. Several patients may be on prescriptions warranting them to be on multiple medications at the same time. However due to personal reasons or beliefs they may be selective in following the prescribed order and be adherent to some medications while being non adherent to certain other medications (75).

However despite these limitations the MMAS-8 is a good screening tool that can be used as an aid to identify patients who may be non-adherent to their medications. It has been used across several countries by researchers as well as physicians across various settings and populations to aid in their respective work in relation to medication non adherence. And so we have chosen this as a measure for calculating predictive accuracy in this particular study.

2.6.2 Clinician Rating Scale

The Clinician Rating Scale is a simple ordinal scale of 1-7 that helps a physician or researcher to quantify his/her assessment of the patient's extent of medication adherence(79). According to this scale higher scores would point towards greater medication non adherence. Scores of < 5 were considered to be non-adherent(80).

Level of adherence	Rating
Complete refusal	1
Partial refusal or only accepts minimum dose	2
Accepts only because compulsory, or very reluctant / requires persuasion, or questions the need for medication often (e.g. every 2 days)	3
Occasional reluctance (e.g. questions the need for medication once a week)	4
Passive acceptance	5
Moderate participation, some knowledge and interest in medication and no prompting required	6
Active participation, readily accepts, and shows some responsibility for regimen	7

The CRS has shown to be sensitive in two controlled trials looking at compliance therapy where it demonstrated differences in outcome in patients who were receiving compliance therapy as against a non-specific counselling (81,82).

In this researcher's study the CRS is being used as a measure of gold standard to determine the sensitivity and specificity based cut offs.

3. Diagnostic Accuracy Studies

In our present research we aim to validate a newly developed score card. So let's now look into the relevant aspects of what validation means and its relevance to research. Validation involves the testing as well as the adaptation of instruments that measures patient related outcomes where it has not been tested yet. This would fall into the category of diagnostic accuracy studies, which are designed to gather evidence on how well would a particular test identify or even rule out a particular disease or a condition (83).

In the present day clinical practise the use of tests is an absolute necessary right from diagnosing a disease(84) to prognosticating it as well as assessing the response to treatment. And so in such a situation the need for the particular test to be able to produce as well as reproduce what it intends to is of paramount importance. The agony that the patient goes through in being diagnosed falsely positive to a critical condition or the harm that awaits a patient who has been deemed to be falsely negative to a condition cannot be quantified by words. Hence the need for assessing and understanding the properties of a particular study, at a specific threshold, as to its sensitivity and specificity or even its positive or negative predictive value is very relevant.

It would be ideal when comparing two diagnostic tests that they be compared in the same patient. If that would not be possible then at least they ought to be from the same randomized population. This would ensure that the difference observed would be due to the tests and not to the patient (83).

3.1 Sensitivity and Specificity

Certain methods would summarise the so called accuracy of a study at over a range of different thresholds. These would summarise the accuracy over a range for example as the area under the receiver operator curve (ROC).If a diagnostic accuracy test is to be clinically useful, it should help in influencing the management of the patient.

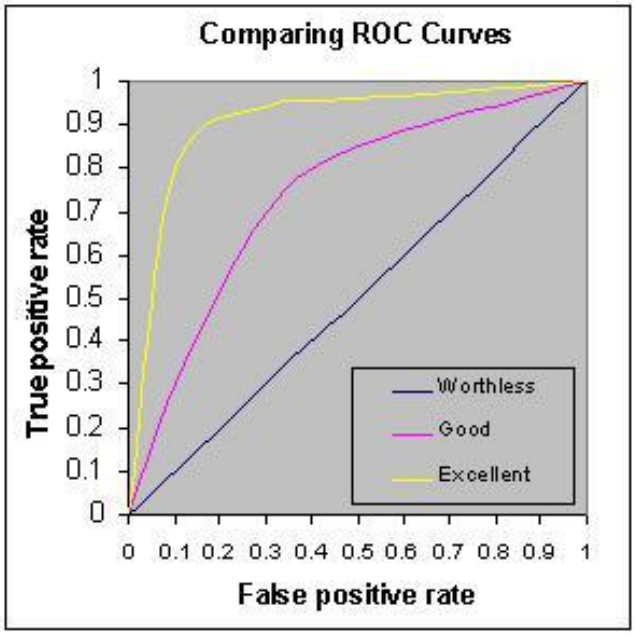


Fig: ROC plot showing excellent, good and worthless curves (85)

The term sensitivity of a test refers to the ability of the test to identify a positive finding when the targeted condition is actually present. This is also referred to as true positive. In other words, it is the ability of the test to identify a condition in a person when the condition is actually there.

The term specificity refers to the ability of a test to identify if the disease or condition is absent when in actuality it is truly is absent. This is also referred to as true negative. These values can be used to arrive at likelihood ratios, both positive and negative. In simpler terms this would mean the ability of the test identify those people as not having the condition when it is actually absent.

3.2 Errors

There also is the need for proper evaluation process in such studies, to reduce the rate of errors(86). Poorly designed studies may lead to diagnosis being inaccurate, treatment being inappropriate as well as errors of judgement while making clinical decisions. Poor methodological issues may lead to poor quality of reporting (87).

Some reasons for such shortcomings in methodology include poor reference standard, selection bias, absence of rater blinding insufficient definitions for positive negative and indeterminate findings (88).

Diagnostic accuracy studies may be done for a newly developed instrument or it may also be applied in new diseases where it may not have been applied yet or even in new populations or languages. This also involves test retest reliability, internal consistency as well as validity.

This process involves comparing the new test with another which would be the gold standard and verifies whether the new test will be able to produce desirable results in comparison. This construct is referred to as validity (89).

It needs to be understood that validity is distinct from reliability. While validity refers to whether the desired test measures what it sets out to measure originally, reliability refers to whether the test does so consistently. So putting into perspective, if a clock was unable to show the time it would be invalid. However, if it was on certain occasions slow and on other occasions fast it would be deemed to be unreliable. If a clock was consistently 30 minutes slow then it would be reliable but not valid.

3.3 Convergent and Divergent Validity

Another aspect to be kept in perspective while understanding validity is its two facets. These are referred to as the convergent and divergent validity. By proving the presence of both test is deemed to have a valid construct (90). Convergent validity refers to the

strength of association between independent measures which are designed so as to measure the same construct. Whereas divergent or discriminant validity refers to the poor association between measures that are designed for unrelated constructs (89).

For a measure with good construct validity, attempts must begin right from the initial stage when the construct is defined and various factors are considered to be representative (89). So if a test would have to measure for example psychosis, then the crucial first step would be to define what psychosis would be. In the absence of a precise definition there would be difficulty in distinguishing it from say anxiety or depression.

Messick in his work described that construct validity had six contributors; content relevance and technical quality, theoretical understanding of scores and associated empirical evidence, structural data, generalizability, external correlates and consequences of score interpretation(91).

3.4 Diagnostic Accuracy Studies in Non-Psychiatric Patients

The relevance of such studies occur in the light of the fact that despite the presence of gold standard tests, newly developed tests may serve some benefit such as being a cheaper alternative or as a screening tool. It could also be less invasive or simpler.

In a study conducted in the United States, a newly developed prospectively applicable method for aiding in the classifying of co morbid conditions which could change the risk of mortality in longitudinal studies was conducted and was found to be simple, readily applicable as well as a valid method of doing so (92).

In another study conducted among general medical populations, the validity as well as the reliability of 3 scales was assessed and found to be internally reliable. It was able to look into the reason behind health care utilisation by the general population (93).

The Brief Pain Inventory is a scale which is used to assess pain in patients who were having malignancy. It was a simple tool that could be used in patients for palliative care. This was validated into the German language and was found to be comparable to the original version (94).

Tan et al in a study conducted among patients with chronic intractable non-malignant pain used this scale, which was primarily used for assessing pain in patients with malignancy. Though this tool was translated into different languages this was the first time that it was being used for a different indication (95). As a result they were able to validate the instrument for a new indication.

3.5 Diagnostic Accuracy Studies in Psychiatric Patients

In a study conducted in the state of Kerala under the National Rural Health Mission (NRHM) a self-administered questionnaires for assessing mental health among adolescents in primary-care setting was validated (96). It was the shorter version of the Teen Screen Questionnaire-Mental Health (TSQ-M). The study revealed the shorter version which was newly developed had for a score of ≥ 6 ,a sensitivity of 76%, specificity of 74%, positive likelihood ratio of 2.99, negative likelihood ratio of 0.33, positive predictive value of 6% and a negative predictive value of 82.1%. This was better than the original scale (96).

In another study conducted in a tertiary care centre in Tamil Nadu, Russell et al evaluated the diagnostic accuracy, reliability and validity of Childhood Autism Rating Scale (CARS) (97). The authors assessed that a score of ≥33 in the CARS achieved a sensitivity of 81.4% (95% CI=71.6-89), a specificity of 78.6%, (95% CI=49.2-95.1), a positive likelihood ratio of 3.8 (95% CI=2.8-5.1), a negative likelihood ratio of 0.24 (95% CI=0.08-0.70), a positive predictive value of 95.9%, and a negative predictive value of 40.7%; therefore it was ideal as a screening cut-off score to identify possible cases of autism (97).

In a study by Mona et al the Beck's Depression Inventory (BDI) was studied for the diagnostic accuracy, reliability and validity when used by paediatricians (98). The authors observed that a cut-off score of ≥ 5 had a sensitivity of 90.9% and specificity

of 17.6 % for screening. With a cut-off score of ≥ 22 the sensitivity was 27.3% and specificity 90% for diagnosis. They concluded that it was a psychometrically valid tool for screening depression in adolescents in a primary care setting (98).

In yet another study a Sinhalese translation of the Impact of Event Scale- 8 items version (IES-8) for use in Sri Lanka was validated (99). This was a cross sectional study that was conducted in rural south Sri Lanka to survivors of the tsunami. A cut-off score of 15 gave a sensitivity of 77% for screening purposes.

Mammen et al developed and validated a concise, parent-completed Brief Intellectual Disability Scale (BIDS) for children to be used in countries with low–disability resource and high–disability care burden (100). It was a prospective cross sectional study. They concluded that BIDS scores of ≥5 had sensitivity of 71.43% and specificity of 80.95%, while scores of ≥11 had sensitivity of 4.29% and specificity of 100%.

3. Justification

The problem of medication non adherence is significant in terms of the impact on the patients, their families and the larger society. Currently there are no standard measures or tools to predict the possibility of non-adherence in a patient. The available tools only help in assessing the problem after it has happened. A standardised tool to predict this problem would help in implementing specific measures and strategies before the non-adherence actually occurs and saves resources as well as prevent unnecessary distress to patients and their families.

4. Aims and Objectives

4.1 Aim

The aim of this study is to evaluate the predictive validity of a newly developed score card to assess medication non adherence in children and adolescents with psychiatric disorders attending a tertiary care hospital in Vellore.

4.2 Objectives

1. To measure the predictive ability of the score card by comparing with the gold standard test after a period of 3 months
2. To measure the convergent and divergent validity of the score card
3. To assess the inter rater reliability of the score card

5. Materials and Methods

5.1 Setting and Participants

The setting for the study was the Child and Adolescent Psychiatry Unit, Department of Psychiatry, Christian Medical College, Vellore. This is a tertiary care centre in South India without any geographically defined catchment population. The unit has two divisions, one for children with emotional and behaviour problems and the other for children with developmental disorders. The study included children from both the divisions. The study was conducted from January 2015 till the sample size is achieved.

5.2 Study Population

The study population in this study was children with emotional or behavioural disorders who enrolled for out-patient review consultation and management in the Child and Adolescent Psychiatry Unit. Those participants who satisfied the selection criteria formed the study sample.

5.3 Sample Size

Regression methods - Multiple logistic regression

Proportion of disease	0.5	0.2	0.5	0.2
Anticipated odds ratio	2	2	1.5	1.5
Power (1- beta) %	80	80	80	80
Alpha error (%)	5	5	5	5
1 or 2 sided	2	2	2	2
Multiple correlation coefficient of the exposure variable with the confounders	0.3	0.3	0.3	0.3
Required sample size	99	149	229	383
Sample size		150		

Required sample size to show that the new tool is able to show non-adherence was found to be 150 children, with 80% power and 5% level of significance and a prevalence of about 20% of non-adherence.

5.4 Selection Criteria

5.4.1 Inclusion Criteria:

1) Age between 3 and 18 years of age.

2) Those with various psychiatric disorders according to International Statistical Classification of Diseases and Related Health Problems 10th Revision.

3) Those who are on psychotropic medications.

4) Patients who are attending the new or review outpatient clinic in CAP unit.

5) Either the patient or the primary caregiver should have a working knowledge of Tamil and English.

5.4.2 Exclusion criteria:

1) Those who are not accompanied by a reliable caregiver to give medication adherence history.

2) Those children unwilling for a written informed consent by the parent.

5.5 Sampling Technique

All consecutive patients who are registered under the Child and Adolescent Psychiatry unit and who satisfy the selection criteria will be recruited into the study.

5.6 Study Design

This is a prospective longitudinal study where the Vellore score card was validated.

5.7 Measures

5.7.1 Vellore Score Card for Adherence to medications

This is a score card for medication non adherence developed in the Child and Adolescent Psychiatry Department at CMC Vellore. The score card building was based on the odds ratio (OR) and the clarity of the 'predictiveness' by being picked-up by more than one measure for the medication adherence. The OR was taken as a 'risk factor' if it was >1 and as 'protective factor' if it was <1. Each risk factor was given the same weightage as the OR but was rounded to the decimal. However, for the protective factors for each 0.25 reduction in the OR a score of 0.25 was given. The score card is given below.

Predictive factor	Odds ratio		Weightage		Score	Modifiability
	CRS	MMAS	OR	Scales		
Boys	-	2.74	3	-	3	Unmodifiable
Illiterate	0.18	-	-0.75	-	-0.75	Modifiable
Primary School Education	0.17		-0.75	-1	-1.75	Modifiable
Middle School Education	0.071	0.076	-1.25	-1	-2.25	Modifiable
Socio economic Status:						
Upper middle		0.16	-0.75		-0.75	Modifiable
Lower middle		0.005	-10.5		-10.5	Modifiable
Upper lower	0.091	0.11	-2.0	-1	-3	Modifiable
Continuous nature of illness	2.6	3.82		+1	+7.5	Non modifiable
BPAD	0.22				-0.75	Modifiable
Depression		2.9			+3	

5.7.2 Comparing other tools for medication adherence

Given below in the table are various the tools used for measuring non adherence to medication.

Scale	Author	Sensitivity	Specificity
MMAS	Morisky	93	53
CRS	Kemp	NA	NA
MAQ	Morisky	81	44
BARS	Byerly	73	74
MARS	Thomson	NA	NA

Table: MMAS – Morisky' Medication Adherence Scale; CRS – Clinician Rating Scale; MAQ – Medication Adherence Questionnaire; BARS – Brief Adherence Rating Scale; MARS – Medication Adherence Rating Scale

The MMAS and CRS have been discussed earlier. The MAQ was originally developed by Morisky and his colleagues towards assessing medication adherence. This was done in a population of hypertensives and shown to have good predictive validity. It has been used by several researchers as well. However psychometric analyses have shown only mixed results (101).

The BARS was developed by Byerly and colleagues(102). It was introduced with a simple description of a clinical rating scale for adherence that could be done with merely a pencil and a paper. It consisted of only 3 questions which was adapted from a questionnaire which was used in the CATIE trial. These questions assessed the patients knowledge about his medication patterns. The adherence was finally measured via a visual analogue scale.

The MARS was developed by Thomson and his colleagues which incorporated features from the MAQ and another scale called the Drug Attitude Inventory (DAI) (103). It was proposed to have a better validity and clinical utility. It consisted of a simple 10 item questionnaire.

As there is currently no measure that is considered as a gold standard test for measuring non adherence, we have decided to consider the CRS scale as the gold standard test in our study.

5.7.3 Kuppusamy Socioeconomic Scale

In our study we have used the Kuppusamy socioeconomic scale modified for the year 2014 by Sukhvinder Singh Oberoi(104)for the purpose of measuring socioeconomic status.

Education	**Score**
Professional or Honours	7
Graduate or Postgraduate	6
Intermediate or post high school diploma	5
High school certificate	4
Middle school certificate	3
Primary school certificate	2
Illiterate	1
Occupation	**Score**
Professional	10
Semi professional	6

Clerical, shop owner, farmer	5
Skilled worker	4
Semi-skilled worker	3
Unskilled worker	2
Unemployed	1
Monthly family income	**Score**
≥36,997	12
18,498-36,996	10
13,874-18,497	6
9,249-13,873	4
5547-9248	3
1866-5546	2
≤1865	1

Based on the above scoring system the scores for various socioeconomic classes are as follows.

Socioeconomic Class	Score
Upper class	26-29
Upper middle class	16-25
Lower middle class	11-15
Upper lower class	5-10
Lower class	<5

5.7.4 Child Sleep Habits Questionnaire

This questionnaire is used in the present study to assess the divergent validity of the score card.Following are a few relevant details regarding its development and use.

The Child Sleep Habits Questionnaire was developed in the United States as a screening tool for measuring sleep disorders in children (105). It is a parent based report for school children(106). It gives a total score as well as eight subscale scores

that cover significant sleep domains in children. This includes both medical as well as behavioural sleep disorders.

The eight subscales include bedtime resistance, sleep-onset delay, sleep duration, sleep anxiety, night wakening, parasomnias, sleep disordered breathing and daytime sleepiness (105). The items under each of these are score on a 3 point scale. Accordingly a higher score indicates sleep pathology. A cut off score of 41 has a sensitivity of 82% and specificity of 72% (106).

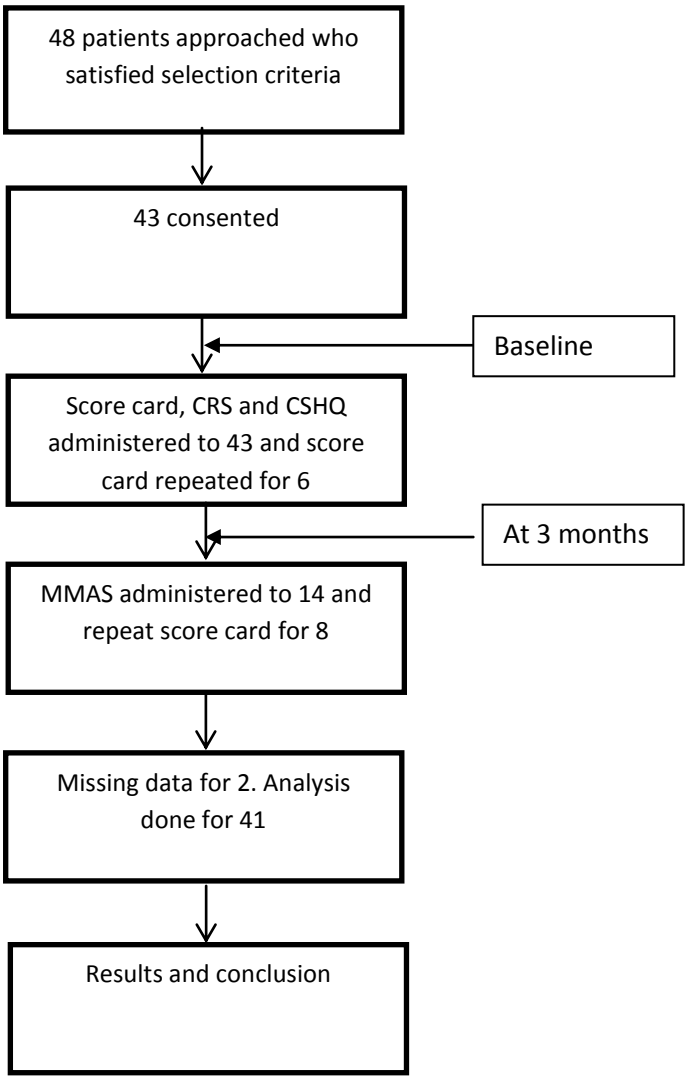
The CSHQ is a well validated tool that has been used in different countries and has been translated into several languages.

5.8 Interview and Assessment

All children and adolescents attending the review OP clinic of Child and Adolescent Unit, during the study period starting from January 2015, till the sample collection calculated *a priori* was completed, was enrolled in to the study if they fulfilled the selection criteria. At the time of enrolment the Score card followed by the CRS, which was the gold or reference standard and CSHQ measures for divergent validity was administered by Rater 1. Simultaneously about 20% of the children was administered the score card by Rater 2 to collect the data on inter-rater reliability. After 3 months the

measure for predictive validity the MMAS-8 was administered by Rater 3. At this time, Rater 1 reassessed 20% of the children with the score card for collecting the data on the test-retest reliability.

The detailed diagrammatic algorithm for the study was as follows.



5.9Statistical Analysis

The frequencies and percentages for the categorical variables which were the age, duration of illness, duration of treatment, number of classes of medications and the distance of home from the hospital was calculated. Mean with standard deviation was calculated for continous variables which were gender, religion, socioeconomic status, diagnosis, co morbid illnesses, family type, parent education and parent occupation. The inter rater and test retest reliability of the new tool was calculated using Intra class Coefficient Correlation. Diagnostic accuracy of the tool was determined by ROC analysis and contingency tables. The cut off points for identifying the cases was obtained by plotting ROC curve with the CRS tool as the reference standard.. The divergent validity was done by using Pearsons correlation in comparison with the child sleep habit questionnaire (CSHQ). Chi square analysis and kappa value was obtained for measuring the predictive value of the Scorecard using the dichotomised Vellore score card and the MMAS -8. Factor validity was derived using factor analysis which was done by Extraction and Rotation method to look into the correlation between the variables of the Vellore score card

6. Results

The results will be discussed under the following headings of participant characteristics, diagnostic accuracy, reliability of measures used and the validity of score card.

About 48 patients who met the selection criteria were approached initially. Among these only 43 consented to the study. Among the 43 who consented 2 had missing data and so were excluded from the final analysis.

6.1 Sociodemographic data

Table1: Patient and family characteristics for the sample

Variable	Frequency (percent)
Sex	
Male	29 (70.7)
Female	12 (29.3)
Religion	
Hindu	37 (90.2)
Muslim	2 (4.9)
Christian	2 (4.9)

Socioeconomic status	
Upper class	3 (7.3)
Upper middle class	4 (9.8)
Lower middle class	12 (29.3)
Upper lower class	21 (51.2)
Diagnosis	
Acute Psychosis	1 (2.4)
Schizophrenia	5 (12.2)
Depression	4 (9.8)
BPAD	4 (9.8)
OCD	4 (9.8)
Adjustment disorder	2 (4.9)
Enuresis	1 (2.4)
ADHD	2 (4.9)
Intellectual Disability	15 (36.6)
Autism	3 (7.3)
Co-morbid conditions	

No Co morbidity	31 (75.6)
Depression	3 (7.3)
ADHD	4 (9.8)
Intellectual Disability	2 (4.9)
Seizure disorder	1 (2.4)
Parent education	
Illiterate	2 (4.9)
Primary school	4 (9.8)
Middle school	2 (4.9)
High school	20 (48.8)
Intermediate/diploma	7 (17.1)
Graduate or post graduate	4 (9.8)
Professional or honours	2 (4.9)
Family type	
Nuclear	15 (36.6)
Joint	9 (22)
Extended	3 (7.3)

Table 2: Patient and family characteristics for the sample contd...

Variable	Mean (std deviation)
Age in years	11.8 (4.75)
Duration of illness in months	49.44 (41.11)
Duration of treatment in months	20.37 (15.03)
Number of classes of medications	1.97 (1.04)
Distance from hospital in kilometres	172.76 (327.06)

In the sample there was a male preponderance with a mean (sd) chronological age of 11.8 (4.75) years. The population was predominantly from an upper lower class background and a large majority were from a Hindu background. The recruited sample came from a far range of distance with a mean distance (sd) from the hospital of 172.76 (327.06) kilometres. Around one third (36.6%) of the patients had a diagnosis of intellectual disability who were on medications for co morbidities. The majority of the sampled population (75.6%) did not have any co morbid illnesses. The mean (sd) duration of illness in months was 49.44 (41.17) and the mean duration (sd) of treatment was 20.37 (15.03). The mean number of classes of medicines was 1.9 (1.04).

6.2 Diagnostic Accuracy

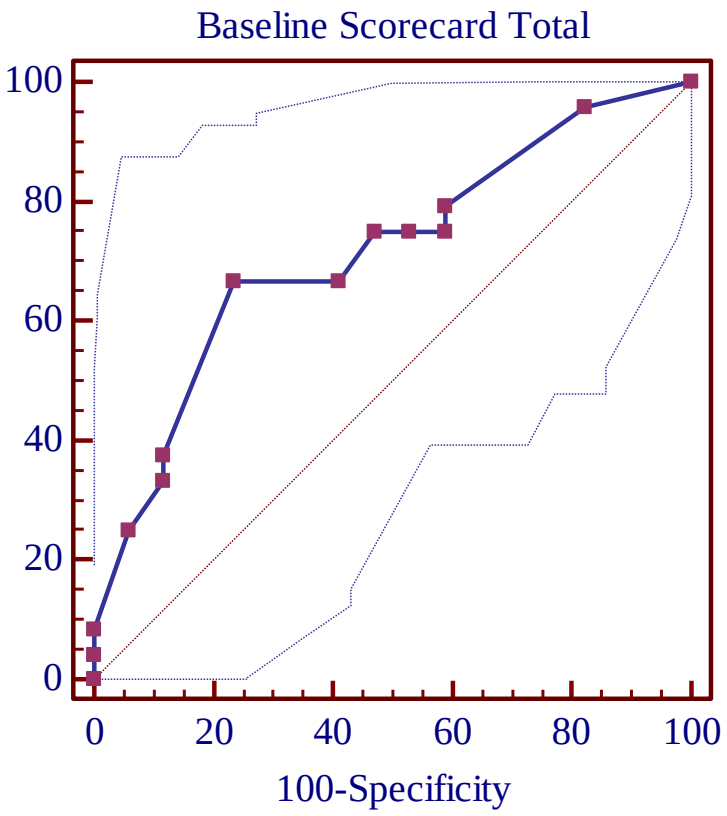


Figure 1: ROC curve

Table 3: Summary of the diagnostic accuracy of the Score Card for the three month Predictive validity based on Clinician Rating Scale as the Gold standard.

Variable		scorecard_baseline Baseline Scorecard Total
Classification variable		CRS_di
Sample size		41
Positive group :	CRS_di = 1	24
Negative group :	CRS_di = 0	17
Disease prevalence (%)		58.5
Area under the ROC curve (AUC)		0.714
Standard Error[a]		0.0811
95% Confidence interval[b]		0.552 to 0.844
z statistic		2.644
Significance level P (Area=0.5)		0.0082

[a] DeLong et al., 1988

[b] Binomial exact

Table 4: Criterion values and coordinates of the ROC curve

Criterion	Sensitivity	95 % CI	Specificity	95 % CI	+ LR	95 % CI	- LR	95 % CI	+PV	95 % CI	- PV	95 % CI
>=-13.5	100.00	85.8 - 100.0	0.00	0.0 - 19.5	1.00				58.5	42.1 - 73.7		
>-13.5	95.83	78.9 - 99.9	17.65	3.8 - 43.4	1.16	0.4 - 3.3	0.24	0.03 - 1.6	62.2	44.5 - 77.7	75.0	13.2 - 99.8
>-10.5	79.17	57.8 - 92.9	41.18	18.4 - 67.1	1.35	0.7 - 2.5	0.51	0.2 - 1.2	65.5	45.7 - 82.1	58.3	27.7 - 84.8
>-8.25	75.00	53.3 - 90.2	41.18	18.4 - 67.1	1.27	0.7 - 2.4	0.61	0.3 - 1.3	64.3	43.7 - 81.6	53.8	25.1 - 80.8
>-	75.00	53.3 -	47.06	23.0 -	1.	0.8 -	0.	0.2 -	66.	45.6 -	57	28.9 -

7.75		90.2		72.2	42	2.5	53	1.2	7	83.8	.1	82.3
>-7.5	75.00	53.3 - 90.2	52.94	27.8 - 77.0	1.59	1.0 - 2.6	0.47	0.2 - 1.1	69.2	47.8 - 86.0	60.0	32.3 - 83.7
>-4.75	66.67	44.7 - 84.4	58.82	32.9 - 81.6	1.62	1.0 - 2.6	0.57	0.3 - 1.3	69.6	46.5 - 87.1	55.6	30.8 - 78.5
>-3.75 *	66.67	44.7 - 84.4	76.47	50.1 - 93.2	2.83	1.9 - 4.2	0.44	0.2 - 1.2	80.0	55.6 - 94.5	61.9	38.4 - 81.9
>-3	37.50	18.8 - 59.4	88.24	63.6 - 98.5	3.19	1.8 - 5.5	0.71	0.2 - 2.7	81.8	46.3 - 98.1	50.0	31.3 - 68.7
>-2.25	33.33	15.6 -	88.24	63.6 -	2.83	1.6 -	0.76	0.2 -	80.0	42.2 -	48.4	30.2 -

		55.3		98.5		5.1		2.9		97.9		66.9
>-0.75	25.00	9.8 - 46.7	94.12	71.3 - 99.9	4.25	2.1 - 8.6	0.80	0.1 - 5.4	85.7	42.1 - 99.6	47.1	29.5 - 65.1
>0	8.33	1.0 - 27.0	100.00	80.5 - 100.0			0.92		100.0	2.5 - 100.0	43.6	27.6 - 60.6
>3	4.17	0.1 - 21.1	100.00	80.5 - 100.0			0.96		100.0	50.0 - 100.0	42.5	26.9 - 59.3
>6	0.00	0.0 - 14.2	100.00	80.5 - 100.0			1.00				41.5	26.3 - 57.9

* Criterion corresponding with highest Youden index

The sensitivity, specificity, likelihood ratios and different predictive values for different cut off points on the Vellore score card for medication adherence were tested against the dichotomised (based on the cut off of less than or equal to 5 as poor adherence) CRS which was considered the gold standard. Table 4 summarizes these results. A score of 0 was taken as the cut off score as it had a specificity of 100% making the score card a valid tool to predict non adherence. However its sensitivity was only 8.33% at this cut off. The area under curve (AUC) in the ROC of the score card was 0.714 (z is 2.644, p=0.0082).as noted in figure 1.

6.3 Reliability

Table 5: Test –retest reliability of the Score Card

	Intraclass Correlation[a]	95% Confidence Interval		
		Lower Bound	Upper Bound	P value
Test-retest reliability	0.51	-1.44	0.90	0.18

[a]=Two-way mixed effects model where people effects are random and measures effects are fixed.

Table 6: Inter-rater reliability of the Score Card

	Intraclass Correlation[a]	95% Confidence Interval		P value
		Lower Bound	Upper Bound	
Inter-rater reliability	.767[c]	-.668	.967	0.07

[a]=Two-way mixed effects model where people effects are random and measures effects are fixed.

The test retest reliability and the inter rater reliability were studied to assess the reproducibility of the score card and the ICC was respectively 0.51 (p=0.18) and 0.77 (0.07). According to Halgren et al the ICC scores for inter rater reliability is excellent

6.4 Validity

6.4.1 Divergent validity

Divergent validity of the Score card against the Children's Sleep Habit Questionnaire (with and without resampling)

Table 7 shows the divergent validity as calculated by correlating the score card with the child sleep habit questionnaire showed no significant association (r= - 0110, p = 0.492). This proves that both the score card and the CSHQ diverge conceptually.

	Baseline Score Card	**CSHQ**	**Confidence Intererval**	**P value**
Baseline Score Card	1	.110	95%	.492
CSHQ	.110	1	95%	.492

6.4.2 Predictive validity

There was no statistical difference between the scores of the vellore score card and the modified morisky's scale both of which were administered at follow up (chi square – 1.143, p=1). However the kappa showed a case identification concordance of .1 (kappa= .25, p=.285).

6.4.3Factor analysis

Table 8: Total Variance Explained

Component	Initial Eigen values			Extraction Sums of Squared Loadings			Rotation Sums of Squared Loadings[a]
	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %	Total
1	2.433	24.335	24.335	2.433	24.335	24.335	2.028
2	1.787	17.865	42.200	1.787	17.865	42.200	1.986
3	1.416	14.161	56.361	1.416	14.161	56.361	1.615
4	1.172	11.722	68.083	1.172	11.722	68.083	1.272
5	1.086	10.865	78.948	1.086	10.865	78.948	1.184
6	.884	8.842	87.790				
7	.571	5.707	93.497				
8	.454	4.543	98.040				
9	.112	1.117	99.157				
10	.084	.843	100.000				

Extraction Method: Principal Component Analysis.

a. When components are correlated, sums of squared loadings cannot be added to obtain a total variance.

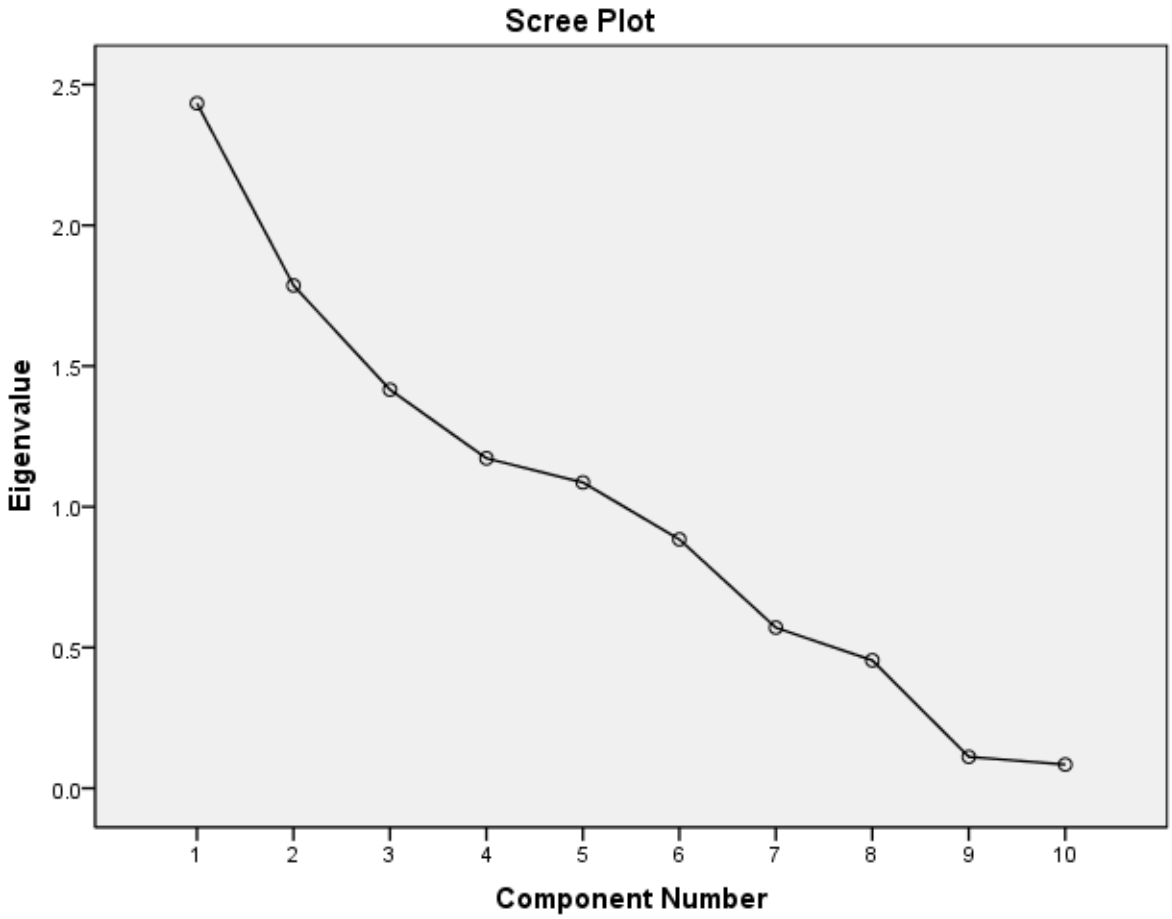


Figure 2: Scree plot for

Table 9: Structure Matrix

	Component				
	1	2	3	4	5
Sex	-.634	-.126	-.153	.412	.305
Parents Illiteracy	-.023	.147	-.052	.023	.893
Parents Primary School Education	.330	.551	-.241	.422	-.268
Parents Middle School Education	-.076	.239	.741	-.111	-.221
Upper Middle SES	.160	-.036	-.104	-.856	-.054
Lower Middle SES	.135	-.882	-.109	.275	-.090
Upper Lower SES	-.188	.873	.179	.260	.167
Continuous Illness	.843	-.091	-.420	-.125	-.269
BPAD	-.087	-.065	.866	.127	.133
Depression	.845	-.182	-.032	.058	.214

Extraction Method: Principal Component Analysis.

Rotation Method: Oblimin with Kaiser Normalization.

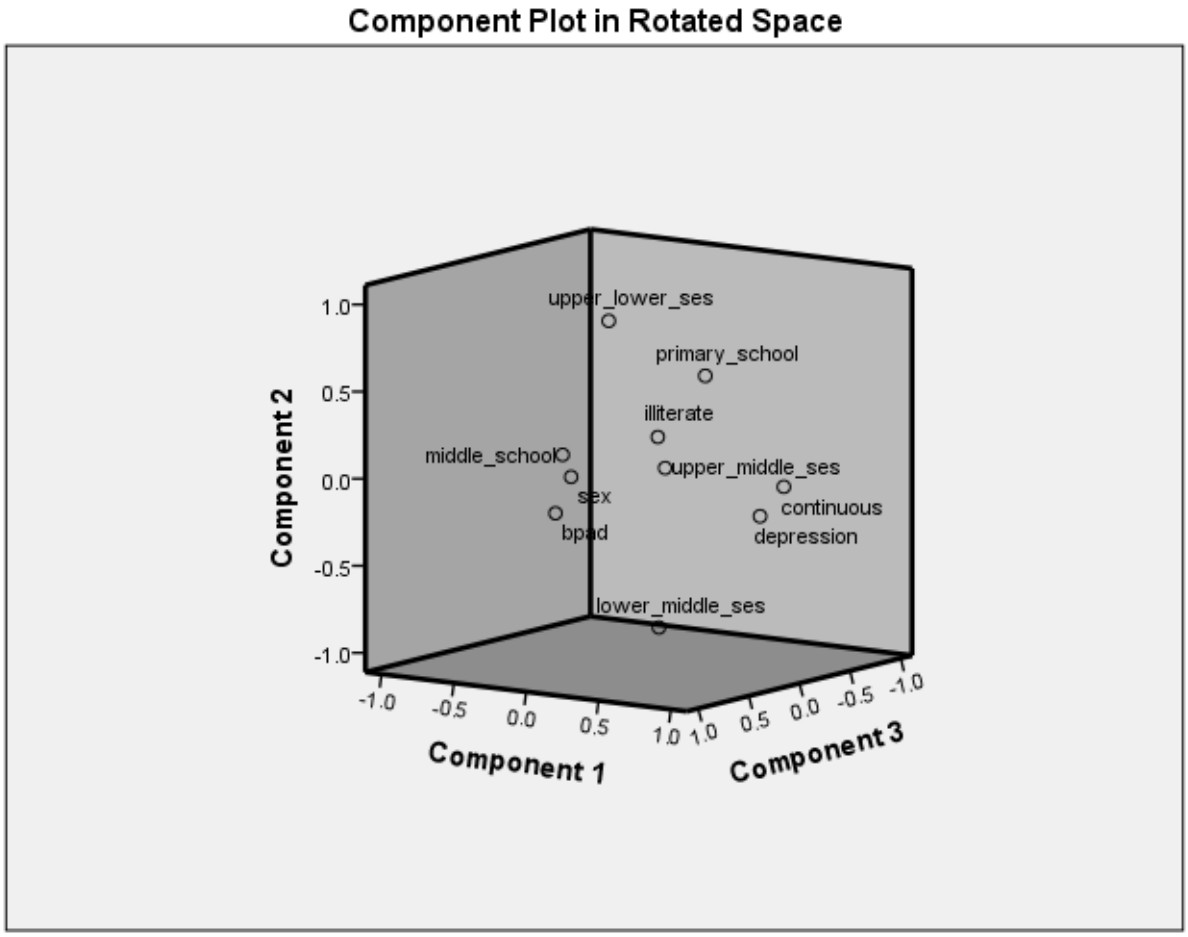


Figure 3: Component plot

Factor validity of the score card was carried out using the extraction and rotation methods. Five different factors were identified. However the items were found to not clearly load into any specific pattern. This could be due to the inadequate sample.

7. Discussion

The Vellore score card for adherence to medications is the first time that a measure has been used to attempt to predict medication non adherence in all patients. Currently existing measures aim to capture the problem after it has occurred leading to significant dysfunction, distress and added costs as has been discussed initially. This specific score card was devised following a previous study undertaken by another researcher who was looking into various factors linked with medication non adherence in children and adolescent population with psychiatric disorders.

As has been well established medication adherence is a well known fact among children as much as it is in the adult population. Hence any relapse is a significant burden on the family as well as the nation's resources. In a developing country like India where resources are scarce to come by whether in terms of healthcare, financial or any other, it would be prudent to say that any method to cut short this menace would be welcome. And it is in this gap that the score card falls in place as a method of cutting short this problem. If the score card is able to accurately pick up the possible children who are going to be non adherent to medications, then specific strategies to deal with it can be initiated. Hence this current study attempted to validate the same score card. At present this study is an ongoing study and is yet to be completed.

Majority of the sampled patients were boys, which was as expected. This could be due to the fact that boys are preferentially taken to the hospital for consultations versus a

girl child. There may be other reasons such as the boy child being expected to be the income generator for the family in the future. Also the fact that, in the case of a girl child the stigma of having a mental illness could greatly affect the future marriage prospects and hence they would be not be brought to the hospital for such fears may be considered.

Most of the patients were from a upper lower socioeconomic status family which is consistent with the location as well as the overall financial situation of the country. The patients had come from far ranging places which included far extreme places of the country and even neighbouring foreign nations. This could be due to the reason that the hospital where the study was conducted was a premier referral institute which targeted not just the immediate surrounding areas. Also the fact that the health care resources of the country not being well developed, the need to travel far to access quality health care is well understood.

The majority of the patients were from a Hindu background which was also consistent with the sociodemographic profile of the country. Most parents were educated up to high school and belonged mostly to a nuclear family followed by a joint family.

About one third of the patients were having intellectual disability. Schizophrenia, depression, bipolar disorders and OCD were the next most common diagnoses. The

other diagnoses included acute psychosis, adjustment disorder, ADHD and autism. This range of illnesses covered could give a better view of the problem as there was no undue focus on any one illness. Also the majority of the sampled patients, which was about 75% did not have any co morbid illnesses which again could show the effect of how a single illness can have in the case of medication adherence.

In comparison to the gold standard which was the clinician rating scale (CRS) the cut off for the Vellore score card was considered at 0. This gave a specificity of 100% as against a sensitivity of 8.33%. This was done as the tool was designed to be a highly specific tool to predict non adherence and be used to devise or implement specific strategies in such children. In a resource strapped country this would help divert the focus to only such patients who would require this and prevent wasting precious resources in others who were less likely to do so.

As was expected the measures of divergent validity which was the child sleep habit questionnaire was shown to have no correlation with the Vellore score card for medication adherence. This shows that the two scales are unrelated and measuring different constructs.

According to Halgren et al various ranges of ICC value have been classified for inter rater reliability (108). According to them values that fall lesser than .40 are poor while

fair and good for values between .40 and .59 as well as .60 and .74 respectively. Those values that fall between .75 and 1.0 are deemed to be excellent. From this standard the Vellore score card had excellent inter rater reliability.

However in the case of test retest reliability; Weir has commented in his review article that it is difficult to comment on classifying the reference ranges of the same using ICC (109). He commented that universal standards for test score reliability may not be feasible as it would also depend on the kind of method used to derive the value and also the ICC would also depend upon the variability in the data. And so in the event of low subject variability the ICC values could be suppressed. Also the socioeconomic status is a factor that can change by drop in income or change in profession of the parents. And hence this also could explain the reason as to why the test retest reliability was low. Hence we choose to not consider the ICC of test retest reliability of the Vellore score card as significant.

8. Strengths and limitations

8.1 Strengths

This is the first time that a study is attempting to develop a predictive tool for medication adherence. Also this tool has been developed specifically for non-adherence to medications in children and adolescents with psychiatric medications. The study does not focus onto any particular psychiatric disorder and rather includes all possible disorders.

8.2Limitations

We observed the following limitations to our study.

The current results are based on the limited sample size and hence cannot be used to finally conclude. As the study will be continued, it is to be seen n the future whether there is any significant result that may occur.

Also the score card currently uses mostly non modifiable factors and this may limit its application as there may be other factors that can be linked to medication adherence which may also have some predict value. This may need to be looked into further.

Currently the reference standards that are being used as gold standard, namely the Clinician rating scale (CRS) for the comparison are measures that are not specific to psychiatric disorders. This may also be a possible area of concern.

Generalisabilty of the study is also in question as the scales used are not validated in our setting, and the study was done in a limited sample size

9. Conclusions

A measure to capture the problem of medication adherence before it happens is truly the need of the hour. This study aims to fill in that void by validating a recently developed score card that aims to predict medication non adherence in children and adolescents with medications for psychiatric disorders. The study compared the score card with the reference standard of Clinician Rating Scale and derived a cut off score card with 100% specificity so as to accurately predict non adherence to medications and allow appropriate interventions to be put in place prior to the onset of the problem and thereby reduce the associated problems of relapse, loss of resources etc. this becomes especially true in a country such as India were finances and access to health care is limited for a majority of patients. The study found the score card to have good interrater reliability and fair test retest reliability. However the predictive accuracy was not significant. This could be due to the fact that the study is yet to be completed and with completion the results could very well turn out to be significant.

10. References

1. Lindberg MJH, Andersen SE, Christensen HR, Kampmann JP. [Compliance to drug prescriptions]. Ugeskr Laeger. 2008 May 26;170(22):1912–6.

2. Eduardo Sabaté. ADHERENCE TO LONG-TERM THERAPIES - Evidence for Action [Internet]. World Health Organisation; 2003. Available from: http://whqlibdoc.who.int/publications/2003/9241545992.pdf

3. DiMatteo MR. Evidence-based strategies to foster adherence and improve patient outcomes. JAAPA Off J Am Acad Physician Assist. 2004 Nov;17(11):18–21.

4. Wahl LM, Nowak MA. Adherence and drug resistance: predictions for therapy outcome. Proc R Soc B Biol Sci. 2000 Apr 22;267(1445):835–43.

5. Boudes P. Drug compliance in therapeutic trials: a review. Control Clin Trials. 1998 Jun;19(3):257–68.

6. Vermeire E, Hearnshaw H, Van Royen P, Denekens J. Patient adherence to treatment: three decades of research. A comprehensive review. J Clin Pharm Ther. 2001 Oct;26(5):331–42.

7. Brown MT, Bussell JK. Medication Adherence: WHO Cares? Mayo Clin Proc. 2011 Apr;86(4):304–14.

8. Haddad PM, Brain C, Scott J. Nonadherence with antipsychotic medication in schizophrenia: challenges and management strategies. Patient Relat Outcome Meas. 2014;5:43–62.

9. Stimson GV. Obeying doctor's orders: a view from the other side. Soc Sci Med. 1974 Feb;8(2):97–104.

10. Barofsky I. Compliance, adherence and the therapeutic alliance: steps in the development of self-care. Soc Sci Med. 1978 Sep;12(5A):369–76.

11. Royal College of General Practitioners (UK). Medicines Adherence: Involving Patients in Decisions About Prescribed Medicines and Supporting Adherence [Internet]. UK: NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE; 2009. Available from: http://www.ncbi.nlm.nih.gov/books/NBK55435/

12. Düsing R, Lottermoser K, Mengden T. Compliance with drug therapy-new answers to an old question. Nephrol Dial Transplant Off Publ Eur Dial Transpl Assoc - Eur Ren Assoc. 2001 Jul;16(7):1317–21.

13. Myfanwy Morgan RH. Concordance, adherence and compliance in medicine taking [Internet]. UK: NHS National Coordinating Centre for Service Delivery and Organisation (NCCSDO); 2005 Dec. Available from: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0009/64494/FR-08-1412-076.pdf

14. Medication Adherence Clinical Reference - American College of Preventive Medicine [Internet]. 2011 [cited 2015 Sep 27]. Available from: http://www.acpm.org/?MedAdherTT_ClinRef

15. Mullick MSI, Goodman R. The prevalence of psychiatric disorders among 5-10 year olds in rural, urban and slum areas in Bangladesh: an exploratory study. Soc Psychiatry Psychiatr Epidemiol. 2005 Aug;40(8):663–71.

16. The $289 Billion Cost of Medication Noncompliance, and What to Do About It - The Atlantic [Internet]. [cited 2014 Oct 19]. Available from: http://www.theatlantic.com/health/archive/2012/09/the-289-billion-cost-of-medication-noncompliance-and-what-to-do-about-it/262222/

17. “Improving the sustainability of healthcare systems through better adherence to therapies: a multi-stakeholder approach ” - Adherence - Joint briefing

paper.pdf [Internet]. [cited 2014 Oct 19]. Available from: http://www.eu-patient.eu/Documents/Policy/Adherence-compliance-concordance/Adherence%20-%20Joint%20briefing%20paper.pdf

18. Osamor PE, Owumi BE. Factors Associated with Treatment Compliance in Hypertension in Southwest Nigeria. J Health Popul Nutr. 2011 Dec;29(6):619–28.

19. Adherence Report Final.pdf [Internet]. [cited 2014 Oct 19]. Available from: http://www.pfizer.ie/UserFiles/file/news_releases/Adherence%20Report%20Final.pdf

20. Ghaziuddin N, King CA, Hovey JD, Zaccagnini J, Ghaziuddin M. Medication noncompliance in adolescents with psychiatric disorders. Child Psychiatry Hum Dev. 1999;30(2):103–10.

21. Pogge DL, Singer MB, Harvey PD. Rates and predictors of adherence with atypical antipsychotic medication: a follow-up study of adolescent inpatients. J Child Adolesc Psychopharmacol. 2005 Dec;15(6):901–12.

22. Scivoletto S, Silva TF, Cunha PJ, Rosenheck RA. The impact of psychiatric diagnosis on treatment adherence and duration among victimized children and adolescents in São Paulo, Brazil. Clinics. 2012 Jan;67(1):3–9.

23. Srinath S, Girimaji SC, Gururaj G, Seshadri S, Subbakrishna DK, Bhola P, et al. Epidemiological study of child & adolescent psychiatric disorders in urban & rural areas of Bangalore, India. Indian J Med Res. 2005 Jul;122(1):67–79.

24. Malhotra S, Kohli A, Arun P. Prevalence of psychiatric disorders in school children in Chandigarh, India. Indian J Med Res. 2002 Jul;116:21–8.

25. Malhotra S, Kohli A, Kapoor M, Pradhan B. Incidence of childhood psychiatric disorders in India. Indian J Psychiatry. 2009;51(2):101–7.

26. Bagchi S, Ambe G, Sathiakumar N. Determinants of Poor Adherence to Anti-Tuberculosis Treatment in Mumbai, India. Int J Prev Med. 2010;1(4):223–32.

27. Journal 55 New.pmd - jact14i1p26.pdf [Internet]. [cited 2014 Oct 19]. Available from: http://medind.nic.in/jac/t14/i1/jact14i1p26.pdf

28. Adherence to Pediatric Medical Regimens for Chronic Disease [Internet]. [cited 2014 Oct 26]. Available from: http://www.apadivisions.org/division-54/evidence-based/medical-regimens.aspx

29. McGrady ME, Hommel KA. Medication adherence and health care utilization in pediatric chronic illness: a systematic review. Pediatrics. 2013 Oct;132(4):730–40.

30. R Sagar RB. Attitudes and subjective reasons of medication compliance and noncompliance among outpatients with schizophrenia in India. Internet J Epidemiol [Internet]. 2008 [cited 2015 Sep 27];7(1). Available from: http://ispub.com/IJE/7/1/12323#

31. Srinivasan TN, Thara R. At issue: management of medication noncompliance in schizophrenia by families in India. Schizophr Bull. 2002;28(3):531–5.

32. IndianJPsycholMed363294-8522194_234021.pdf [Internet]. [cited 2015 Sep 10]. Available from: http://www.ijpm.info/temp/IndianJPsycholMed363294-8522194_234021.pdf

33. Lingam R, Scott J. Treatment non-adherence in affective disorders. Acta Psychiatr Scand. 2002 Mar;105(3):164–72.

34. Scott J, Pope M. Nonadherence with mood stabilizers: prevalence and predictors. J Clin Psychiatry. 2002 May;63(5):384–90.

35. DiMatteo MR, Lepper HS, Croghan TW. Depression is a risk factor for noncompliance with medical treatment: meta-analysis of the effects of anxiety

and depression on patient adherence. Arch Intern Med. 2000 Jul 24;160(14):2101–7.

36. Sharma S, Kumar N, Chakraborti S, Sinha S, Kumari S, Gajendragad JM. Prevalence and factors associated with medication compliance in Indian patients suffering from mental disorders. Trop Doct. 2012 Jan;42(1):28–31.

37. Banerjee S, Varma RP. Factors Affecting Non-Adherence among Patients Diagnosed with Unipolar Depression in a Psychiatric Department of a Tertiary Hospital in Kolkata, India. Depress Res Treat. 2013;2013:809542.

38. P - 13.pdf [Internet]. [cited 2014 Oct 26]. Available from: http://www.ijpbs.net/vol-3/issue-1/bio/P%20-%2013.pdf

39. Matsui DM. Drug compliance in pediatrics. Clinical and research issues. Pediatr Clin North Am. 1997 Feb;44(1):1–14.

40. Costello I, Wong ICK, Nunn AJ. A literature review to identify interventions to improve the use of medicines in children. Child Care Health Dev. 2004 Nov;30(6):647–65.

41. Santer M, Ring N, Yardley L, Geraghty AWA, Wyke S. Treatment non-adherence in pediatric long-term medical conditions: systematic review and synthesis of qualitative studies of caregivers' views. BMC Pediatr. 2014;14:63.

42. Sitholey P, Agarwal V, Chamoli S. A preliminary study of factors affecting adherence to medication in clinic children with attention-deficit/hyperactivity disorder. Indian J Psychiatry. 2011 Jan;53(1):41–4.

43. Improve Medication Adherence [Internet]. [cited 2014 Oct 27]. Available from: http://www.mts-mt.com/Why_MTS/Medication_Adherence_Resources.aspx

44. Improving Glaucoma Patient Compliance [Internet]. [cited 2014 Oct 27]. Available from:

http://www.ophthalmologymanagement.com/articleviewer.aspx?articleID=103767

45. Jimmy B, Jose J. Patient Medication Adherence: Measures in Daily Practice. Oman Med J. 2011 May;26(3):155–9.

46. Manteuffel M, Williams S, Chen W, Verbrugge RR, Pittman DG, Steinkellner A. Influence of patient sex and gender on medication use, adherence, and prescribing alignment with guidelines. J Womens Health 2002. 2014 Feb;23(2):112–9.

47. Riaz M, Basit A, Fawwad A, Yakoob Ahmedani M, Ali Rizvi Z. Factors associated with non-adherence to insulin in patients with type 1 diabetes. Pak J Med Sci. 2014;30(2):233–9.

48. Microsoft Word - dissertation final corrections - Dissertation.pdf [Internet]. [cited 2015 May 14]. Available from: http://ir.muhas.ac.tz:8080/jspui/bitstream/123456789/42/1/Dissertation.pdf

49. Kyngäs H. Predictors of good compliance in adolescents with epilepsy. Seizure. 2001 Dec;10(8):549–53.

50. Senior V, Marteau TM, Weinman J, Genetic Risk Assessment for FH Trial (GRAFT) Study Group. Self-reported adherence to cholesterol-lowering medication in patients with familial hypercholesterolaemia: the role of illness perceptions. Cardiovasc Drugs Ther Spons Int Soc Cardiovasc Pharmacother. 2004 Nov;18(6):475–81.

51. Roberson MHB. The Meaning of Compliance: Patient Perspectives. Qual Health Res. 1992 Feb 1;2(1):7–26.

52. Connelly CE. Compliance with outpatient lithium therapy. Perspect Psychiatr Care. 1984 Jun;22(2):44–50.

53. Jin J, Sklar GE, Min Sen Oh V, Chuen Li S. Factors affecting therapeutic compliance: A review from the patient's perspective. Ther Clin Risk Manag. 2008 Feb;4(1):269–86.

54. Shaw E, Anderson JG, Maloney M, Jay SJ, Fagan D. Factors associated with noncompliance of patients taking antihypertensive medications. Hosp Pharm. 1995 Mar;30(3):201–3, 206–7.

55. Dutta S, Biswas N, Muhkherjee G. Evaluation of Socio-demographic Factors for Non-compliance to Treatment in Locally Advanced Cases of Cancer Cervix in a Rural Medical College Hospital in India. Indian J Palliat Care. 2013;19(3):158–65.

56. Gajanan S. Gaude. Factors Affecting Non-adherence in Bronchial Asthma and Impact of Health Education. Indian J Allergy Asthma Immunol. 25(1):1–8.

57. Efficacy of various durations of isoniazid preventive therapy for tuberculosis: five years of follow-up in the IUAT trial. International Union Against Tuberculosis Committee on Prophylaxis. Bull World Health Organ. 1982;60(4):555–64.

58. Sharkness CM, Snow DA. The patient's view of hypertension and compliance. Am J Prev Med. 1992 Jun;8(3):141–6.

59. Sharband R Vemula SS. A study of non-compliance with pharmacotherapy in psychiatric patients. AP J Psychol Med. 15(1):81–5.

60. Raman Kalia BP. Factors affecting Non-compliance to psychotropic drugs of patients with psychosis as perceived by their family members attending the psychiatric outpatient department at selected hospital, Mangalore. Nurs Midwifery Res J. 9(2):56–62.

61. Stephenson BJ, Rowe BH, Haynes RB, Macharia WM, Leon G. The rational clinical examination. Is this patient taking the treatment as prescribed? JAMA. 1993 Jun 2;269(21):2779–81.

62. Treatment non-adherence in affective di... [Acta Psychiatr Scand. 2002] - PubMed - NCBI [Internet]. [cited 2014 Oct 26]. Available from: http://www.ncbi.nlm.nih.gov/pubmed/11939969

63. Gilbert JR, Evans CE, Haynes RB, Tugwell P. Predicting compliance with a regimen of digoxin therapy in family practice. Can Med Assoc J. 1980 Jul 19;123(2):119–22.

64. Jónsdóttir H, Opjordsmoen S, Birkenaes AB, Engh JA, Ringen PA, Vaskinn A, et al. Medication adherence in outpatients with severe mental disorders: relation between self-reports and serum level. J Clin Psychopharmacol. 2010 Apr;30(2):169–75.

65. Liu H, Golin CE, Miller LG, Hays RD, Beck CK, Sanandaji S, et al. A comparison study of multiple measures of adherence to HIV protease inhibitors. Ann Intern Med. 2001 May 15;134(10):968–77.

66. Hui CLM, Chen EYH, Kan CS, Yip KC, Law CW, Chiu CPY. Detection of Non-Adherent Behaviour in Early Psychosis. Aust N Z J Psychiatry. 2006 May 1;40(5):446–51.

67. Ho PM, Bryson CL, Rumsfeld JS. Medication Adherence Its Importance in Cardiovascular Outcomes. Circulation. 2009 Jun 16;119(23):3028–35.

68. Barber N. Should we consider non-compliance a medical error? Qual Saf Health Care. 2002 Mar;11(1):81–4.

69. Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med. 2005 Aug 4;353(5):487–97.

70. Daniel A Hussar. Adherence to a Drug Regimen - Clinical Pharmacology - Merck Manuals Professional Edition [Internet]. Merck Manuals Professional Edition. [cited 2015 Sep 27]. Available from: http://www.merckmanuals.com/professional/clinical-pharmacology/factors-affecting-response-to-drugs/adherence-to-a-drug-regimen

71. Wilk J, Marcus SC, West J, Countis L, Hall R, Regier DA, et al. Substance abuse and the management of medication nonadherence in schizophrenia. J Nerv Ment Dis. 2006 Jun;194(6):454–7.

72. Medication Nonadherence [Internet]. [cited 2015 May 6]. Available from: http://www.medscape.com/viewarticle/409940

73. Olivieri NF, Matsui D, Hermann C, Koren G. Compliance assessed by the Medication Event Monitoring System. Arch Dis Child. 1991 Dec;66(12):1399–402.

74. Raynor DK. Patient compliance: the pharmacist's role. Int J Pharm Pract. 1992 Mar 1;1(3):126–35.

75. POLICY - cop_article_483579.pdf [Internet]. [cited 2015 May 7]. Available from: http://www.pharmacy.umn.edu/innovations/prod/groups/cop/@pub/@cop/@innov/documents/article/cop_article_483579.pdf

76. Morisky DE, Green LW, Levine DM. Concurrent and predictive validity of a self-reported measure of medication adherence. Med Care. 1986 Jan;24(1):67–74.

77. Morisky DE, Ang A, Krousel-Wood M, Ward HJ. Predictive Validity of a Medication Adherence Measure in an Outpatient Setting. J Clin Hypertens. 2008 May 1;10(5):348–54.

78. de Oliveira-Filho AD, Morisky DE, Neves SJF, Costa FA, de Lyra DP. The 8-item Morisky Medication Adherence Scale: validation of a Brazilian-Portuguese

version in hypertensive adults. Res Soc Adm Pharm RSAP. 2014 Jun;10(3):554–61.

79. Montes JM, Maurino J, de Dios C, Medina E. Suboptimal treatment adherence in bipolar disorder: impact on clinical outcomes and functioning. Patient Prefer Adherence. 2013 Jan 18;7:89–94.

80. Mutsatsa SH, Joyce EM, Hutton SB, Webb E, Gibbins H, Paul S, et al. Clinical correlates of early medication adherence: West London first episode schizophrenia study. Acta Psychiatr Scand. 2003 Dec;108(6):439–46.

81. Kemp R, Hayward P, Applewhaite G, Everitt B, David A. Compliance therapy in psychotic patients: randomised controlled trial. BMJ. 1996 Feb 10;312(7027):345–9.

82. Kemp R, Kirov G, Everitt B, Hayward P, David A. Randomised controlled trial of compliance therapy. 18-month follow-up. Br J Psychiatry J Ment Sci. 1998 May;172:413–9.

83. Susan Mallett. Interpreting diagnostic accuracy studies for patient care | The BMJ. 2012 Jul [cited 2015 Sep 27]; Available from: http://www.bmj.com/content/345/bmj.e3999

84. Fritz JM, Wainner RS. Examining diagnostic tests: an evidence-based perspective. Phys Ther. 2001 Sep;81(9):1546–64.

85. The Area Under an ROC Curve [Internet]. Available from: http://gim.unmc.edu/dxtests/roc3.htm

86. Bossuyt PM, Reitsma JB, Bruns DE, Gatsonis CA, Glasziou PP, Irwig LM, et al. The STARD statement for reporting studies of diagnostic accuracy: explanation and elaboration. Ann Intern Med. 2003 Jan 7;138(1):W1–12.

87. Bossuyt PM, Reitsma JB, Bruns DE, Gatsonis CA, Glasziou PP, Irwig LM, et al. Towards complete and accurate reporting of studies of diagnostic accuracy: the STARD initiative. The Standards for Reporting of Diagnostic Accuracy Group. Croat Med J. 2003 Oct;44(5):635–8.

88. Cook C, Cleland J, Huijbregts P. Creation and Critique of Studies of Diagnostic Accuracy: Use of the STARD and QUADAS Methodological Quality Assessment Tools. J Man Manip Ther. 2007;15(2):93–102.

89. Strauss ME, Smith GT. Construct Validity: Advances in Theory and Methodology. Annu Rev Clin Psychol. 2009 Apr 27;5:1–25.

90. Convergent & Discriminant Validity [Internet]. [cited 2015 May 27]. Available from: http://www.socialresearchmethods.net/kb/convdisc.php

91. Messick S. Validity of Psychological Assessment: Validation of Inferences from Persons' Responses and Performances as Scientific Inquiry into Score Meaning. ETS Res Rep Ser. 1994 Dec 1;1994(2):i – 28.

92. Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. J Chronic Dis. 1987;40(5):373–83.

93. Speckens AE, Spinhoven P, Sloekers PP, Bolk JH, van Hemert AM. A validation study of the Whitely Index, the Illness Attitude Scales, and the Somatosensory Amplification Scale in general medical and general practice patients. J Psychosom Res. 1996 Jan;40(1):95–104.

94. Radbruch L, Loick G, Kiencke P, Lindena G, Sabatowski R, Grond S, et al. Validation of the German version of the Brief Pain Inventory. J Pain Symptom Manage. 1999 Sep;18(3):180–7.

95. Tan G, Jensen MP, Thornby JI, Shanti BF. Validation of the Brief Pain Inventory for chronic nonmalignant pain. J Pain Off J Am Pain Soc. 2004 Mar;5(2):133–7.

96. Nair MKC, Rajaraman V, Chacko D, Russell S, George B, Sumaraj L, et al. Comparison of the Diagnostic Accuracy and Validity of a Short Version of Teen Screen Questionnaire-Mental Health (TSQ -M-Short) for Use in Community. Indian J Psychol Med. 2015;37(2):201–4.

97. Russell PSS, Daniel A, Russell S, Mammen P, Abel JS, Raj LE, et al. Diagnostic accuracy, reliability and validity of Childhood Autism Rating Scale in India. World J Pediatr WJP. 2010 May;6(2):141–7.

98. Basker M, Moses PD, Russell S, Russell PSS. The psychometric properties of Beck Depression Inventory for adolescent depression in a primary-care paediatric setting in India. Child Adolesc Psychiatry Ment Health. 2007 Aug 9;1:8.

99. 4052711041164474_manuscript.pdf [Internet]. [cited 2015 May 28]. Available from: http://www.cpementalhealth.com/imedia/4052711041164474_manuscript.pdf

100. Mammen P, Russell PSS, Nair MKC, Russell S, Kishore C, Shankar S. Development and psychometric validation of the Brief Intellectual Disability Scale for use in low–health resource, high-burden countries. J Clin Epidemiol. 2013 Jan 1;66(1):30–5.

101. Toll BA, McKee SA, Martin DJ, Jatlow P, O'Malley SS. Factor structure and validity of the Medication Adherence Questionnaire (MAQ) with cigarette smokers trying to quit. Nicotine Tob Res Off J Soc Res Nicotine Tob. 2007 May;9(5):597–605.

102. Byerly MJ, Nakonezny PA, Rush AJ. The Brief Adherence Rating Scale (BARS) validated against electronic monitoring in assessing the antipsychotic

medication adherence of outpatients with schizophrenia and schizoaffective disorder. Schizophr Res. 2008 Mar;100(1-3):60–9.

103. Fialko L, Garety PA, Kuipers E, Dunn G, Bebbington PE, Fowler D, et al. A large-scale validation study of the Medication Adherence Rating Scale (MARS). Schizophr Res. 2008 Mar;100(1-3):53–9.

104. Sukhvinder Singh Oberoi. Updating income ranges for Kuppuswamy's socio-economic status scale for the year 2014 Oberoi SS - Indian J Public Health. Indoian J Public Health. 2015;59(2):156–7.

105. Waumans RC, Terwee CB, Van den Berg G, Knol DL, Van Litsenburg RRL, Gemke RJBJ. Sleep and Sleep Disturbance in Children: Reliability and Validity of the Dutch Version of the Child Sleep Habits Questionnaire. Sleep. 2010 Jun 1;33(6):841–5.

106. Owens JA, Spirito A, McGuinn M. The Children's Sleep Habits Questionnaire (CSHQ): psychometric properties of a survey instrument for school-aged children. Sleep. 2000 Dec 15;23(8):1043–51.

107. SLEEP - The Children's Sleep Habits Questionnaire (CSHQ): Psychometric Properties of A Survey Instrument for School-Aged Children [Internet]. [cited 2015 May 14]. Available from: http://www.journalsleep.org/ViewAbstract.aspx?pid=25565

108. Hallgren KA. Computing Inter-Rater Reliability for Observational Data: An Overview and Tutorial. Tutor Quant Methods Psychol. 2012;8(1):23–34.

109. Weir JP. Quantifying test-retest reliability using the intraclass correlation coefficient and the SEM. J Strength Cond Res Natl Strength Cond Assoc. 2005 Feb;19(1):231–40.

Participant Information Sheet

Department of Child and Adolescent Psychiatry
Christian Medical College Hospital

Study Title:
NON ADHERENCE IN CHILDREN AND ADOLESCENTS WITH PSYCHIATRIC DISORDERS: VALIDATION OF A NEWLY DEVELOPED SCORE CARD

Children and adolescents with different psychiatric disorders are prescribed medications which some of them do not take regularly. This can affect their long term improvement and recovery from the illness. It is important to know the reasons why they are not taking medications. This knowledge will help us to identify those children who might fail to take medicines and prevent this. A score card has been newly developed to predict non adherence. This will help in putting into practice relevant measures to prevent or limit the occurrence of non adherence. You are being requested to participate in this study.

If you take part what will you have to do?

If you agree to participate in this study, you will be interviewed by the doctors conducting the study. These questions will cover various aspects of taking medications. No additional procedures or blood tests will be conducted for this study.

Can you withdraw from this study after it starts?

Your participation in this study is entirely voluntary and you are also free to decide to withdraw permission even after initial consent to participate in this study. Not participating in this study will not affect your usual treatment at this hospital in any way.

Will your personal details be kept confidential?

The results of this study will be published in a medical journal but you or child will not be identified by name in any publication or presentation of results.

If you have any further questions, please ask:
Dr Sony Mathews Lukose or Dr Paul S S Russell or Dr Priya Mammen,
Child and Adolescent Unit, Department of Psychiatry, CMC, Bagayam,
Vellore, Tamil Nadu
Phone no: 0416 2284307
E-mail: childpsych@cmcvellore.ac.in

Informed Consent to Participate in a Research Study

1. Study Title: MEDICATION NON-ADHERENCE IN CHILDREN AND ADOLESCENTS WITH PSYCHIATRIC DISORDERS: PREDICTIVE ACCURACY, VALIDITY AND RELIABILITY OF A NEWLY DEVELOPED SCORE CARD.

Study Number: _____
Subject's Initials: _____
Subject's Name: _____
Date of Birth / Age: _____
(Subject)

(i) I confirm that I have read and understood the information sheet dated _____ for the above study and have had the opportunity to ask questions. [ ]

(ii) I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. [ ]

(iii) I understand that the Sponsor of the clinical trial, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published. [ ]

(iv) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s). [ ]

(v) I agree to take part in the above study. [ ]

Signature (or Thumb impression) of the Subject/Legally Acceptable

Date: _____/_____/_____

Signatory's Name: _____ Signature:

Or

Representative: _____

Date: _____/_____/_____

Signatory's Name: _____

Signature of the Investigator: _____

Date: _____/_____/_____

Study Investigator's Name: _____

Signature (or) thumb impression of the Witness: _____

Date: _____/_____/_____

Name and Address of the Witness: _____

கிறிஸ்தவ மருத்துவக் கல்லூரி, வேலூர்
மனநல மருத்துவமனை, இளம் பருவ வயதினர் மனநலப் பிரிவு.

ஆய்வின் தலைப்பு:
"மனநோயால் பாதிக்கப்பட்ட குழந்தைகள் மற்றும் இளம் பருவ வயதினர்களுக்கு மருத்துவர்கள் அளிக்கும் மருந்துகளை சரிவர முறையாக தராதவர்களுக்காக:
- புதிதாக உருவாக்கப்பட்ட அளவீட்டு மதிப்பெண் அட்டை பற்றிய ஆய்வு:

ஆய்வின் விளக்கம்:
மனநோயால் பாதிக்கப்பட்டு சிகிச்சைப் பெறும் குழந்தைகள் மற்றும் இளம் பருவ வயதினர்கள், அவர்களுக்கு மருத்துவரால் அளிக்கப்படும் மருந்துகளை ஒருசிலர் முறையாக தினமும் தராமல் தவறிவிடுகிறார்கள். இதனால், தொடர்ந்து நீண்ட நாட்கள் சிகிச்சை பெற்று சுகம் பெற்று முன்னேற்றம் அடையும் நோயாளியின் சிகிச்சை பலனற்று போகிறது. எனவே, ஏன் அவ்வாறு நோயாளிகளுக்கு மருந்துகள் கொடுப்பது தடைப்படுகிறது என்பதை ஆராய்வது அவசியம். அப்படிப்பட்ட பிள்ளைகளை கண்டறிந்து, அவர்களுக்கு உதவுவது மிகவும் அவசியமாகிறது. இதற்காக ஓர் புதிய அளவீட்டு மதிப்பெண் அட்டையை சரிபார்க்க உருவாக்கியுள்ளோம். இந்த சரிபார்க்கும் அளவீட்டு மதிப்பெண் அட்டையை பயன்படுத்துவதின் மூலம், எந்தெந்த சூழ்நிலையில் மருந்துகள் எடுத்துக்கொள்வது தவறிவிடுகிறது என்பதை கண்டுபிடிக்க உதவும். ஆகவே, நீங்கள் இந்த ஆய்வில் கலந்துகொண்டு உதவும்படி உங்களை அன்புடன் வேண்டுகின்றோம்.

ஆய்வில் கலந்துகொள்ளும் நீங்கள் செய்ய வேண்டியது என்ன?
நீங்கள் இந்த ஆய்வில் கலந்துகொள்ள சம்மதித்தால், ஆய்வை நடத்தும் மருத்துவரிடம் நேரடியான கலந்தாலோசனை செய்தல் வேண்டும். நோயாளியின் மருந்துகள் தரப்படும் விபரங்கள் பற்றிய ஒருசில கேள்விகளை மருத்துவர் உங்களிடம் கேட்பார். வேறு எந்த சிகிச்சைகளோ அல்லது ரத்தப்பரிசோதனையோ செய்யப்படமாட்டாது.

ஆய்வு தொடங்கியப் பிறகு இந்த ஆய்விலிருந்து நீங்கள் விலகிக்கொள்ள முடியுமா?
இந்த ஆய்வில் நீங்கள் உங்கள் முழு சம்மதத்துடன் கலந்து கொண்டிருக்கிறீர்கள். எப்போது வேண்டுமானாலும் இதிலிருந்து விலகிக்கொள்ள உங்களுக்கு முழு சுதந்திரம் உள்ளது. இப்படி நீங்கள் விலகிக்கொள்வதால், ஏற்கனவே, உங்கள் குழந்தைக்கு அளிக்கப்படும் எங்கள் மருத்துவ சிகிச்சை எந்த விதத்திலும் பாதிக்கப்படமாட்டாது.

இந்த ஆய்வுவில் நீங்கள் கலந்துகொள்வதால் உங்களைப்பற்றிய விபரங்கள் ரகசியமாக பாதுகாக்கப்படுமா?
ஆய்வில் கலந்துகொள்ளும் உங்கள் பெயர், குடும்ப விபரங்கள் அனைத்தும் ரகசியமாக பாதுகாக்கப்படும். இந்த ஆய்வின் அறிக்கைகள் மருத்துவ ஆராய்ச்சிப் புத்தகங்களில் வெளியிடப்படும். ஆனால் எந்த விதத்திலும் உங்கள் அனுமதியின்றி நோயாளியின் பெயர், குடும்ப அடையாள விபரங்கள் ஆகியவை மிகவும் ரகசியமாக பாதுகாக்கப்படும்.

மேலும் ஆய்வின் விபரங்களை அறிந்துகொள்ள தொடர்புகொள்ள வேண்டியவர்கள்:
டாக்டர். சோனி மேத்யூ லூக்காஸ்
டாக்டர். பால் S.S.ரசல்
டாக்டர். ஷோனிமா.A.V & மிஞ்சு.K.A.
மனநல மருத்துவமனை,
இளம் பருவ வயதினர் மனநலப் பிரிவு,
கிறிஸ்தவ மருத்துவக் கல்லூரி,
வேலூர் - 632 002

தொலைப்பேசி எண்: 0416 - 2284307
மின் அஞ்சல்: childpsych@cmcvellore.ac.in

Participant Information Sheet for Children

Department of Child and Adolescent Psychiatry
Christian Medical College Hospital

Study Title: NON ADHERENCE IN CHILDREN AND ADOLESCENTS WITH PSYCHIATRIC DISORDERS: VALIDATION OF A NEWLY DEVELOPED SCORE CARD

I am Dr Sony Mathews Lukose from Christian Medical College. Children and teenagers with different psychiatric illnesses are prescribed medications which some of them do not take regularly. This is called as non adherence. This can affect their long term improvement and recovery from the illness. It is important to know the reasons why they are not taking medications. This knowledge will help us to identify those children who might fail to take medicines and prevent this. I am doing a study to find out if a particular test that we have created is able to say in advance if a child is likely to no take his medications as advised by the doctor. We are asking you to take part in the research study because knowing the answer to this question will be helpful in identifying such children and

For this research, we will ask you a few simple questions regarding your medication habits as well as your sleep habits. We will keep all your answers private, and will not show them to anyone else. Only people working on the study will see them.

We don't think that any big problems will happen to you as part of this study. Also there will be no blood tests. You only have to answer a few simple questions. Also, you can feel good about helping us to find an answer to this problem and have a part in helping other children.

You do not have to be in this study if you do not want to. You won't get into any trouble for saying no. And even if you say yes, you may stop being in the study at any time. Your parent(s)/guardian(s) were already asked if it is OK for you to be in this study. Even if they say it's OK, it is still your choice whether or not to take part. You can ask any questions you have, now or later. If you think of a question later, you or your parents can contact me at

Dr Sony Mathews Lukose or Dr Paul S S Russell or Dr Minju K A or Dr Shonima Child & Adolescent Unit, Department of Psychiatry, CMC, Bagayam, Vellore, Tamil Nadu, Phone : 0416 2284307; E-mail: childpsych@cmcvellore.ac.in

Sign this form only if you:

1. have understood what you will be doing for this study,

2. have had all your questions answered.
3. have talked to your parent(s)/legal guardian about this project.
4. agree to take part in this research.

_____Your

Signature Name Date

_____

Name of Parent(s) or Legal Guardian(s)

_____

Researcher explaining study

Signature Name Date

Serial No:

1. Name of the patient:
2. Hospital No:
3. Age
4. Gender
5. Contact details of primary caregiver(telephone and postal address)
6. Education of primary caregiver
7. Occupation of primary caregiver
8. Family income per month (in Rs)
9. Distance from the hospital (in kms)
10. Type of the illness
11. Duration of the disorder (in days)
12. Nature of the disorder (relapsing/ continuous) (from data sheet)
13. Presence or absence of co-morbidities (from data sheet)
14. Years of training in Psychiatry (in years)
15. Change of therapist (from data sheet)

Vellore Score Card for Adherence to Medication (Vellore SCAM)	
Predictive factor	Score
Boys	3
Illiterate	-0.75
Primary School Education	-1.75
Middle School Education	-2.25
Occupation of parent	
SES Upper middle Lower middle Upper lower	-0.75 -10.5 -3
Continuous nature of illness	+7.5
BPAD Depression	-0.75 +3

Level of adherence	Rating
Complete refusal	1
Partial refusal or only accepts minimum dose	2
Accepts only because compulsory, or very reluctant / requires persuasion, or questions the need for medication often (e.g. every 2 days)	3
Occasional reluctance (e.g. questions the need for medication once a week)	4
Passive acceptance	5
Moderate participation, some knowledge and interest in medication and no prompting required	6
Active participation, readily accepts, and shows some responsibility for regimen	7

Morisky 8-Item Medication Adherence Questionnaire

Question	Patient Answer Yes/No	Score Y=1; N=0
Do you sometimes forget to take your medicine?		
People sometimes miss taking their medicines for reasons other than forgetting. Thinking over the past 2 weeks, were there any days when you did not take your medicine?		
Have you ever cut back or stopped taking your medicine without telling your doctor because you felt worse when you took it?		
When you travel or leave home, do you sometimes forget to bring along your medicine?		
Did you take all your medicines yesterday?		
When you feel like your symptoms are under control, do you sometimes stop taking your medicine?		
Taking medicine every day is a real inconvenience for some people. Do you ever feel hassled about sticking to your treatment plan?		
How often do you have difficulty remembering to take all your medicine? __ A. Never/rarely __ B. Once in a while __ C. Sometimes __ D. Usually __ E. All the time		A =0; B-E=1
	Total score	

Scores: >2 = low adherence
1 or 2 = medium adherence
0 = high adherence

Morisky DE, Green LW, Levine DM. Concurrent and predictive validity of a self-reported measure of medication adherence.
Med Care. 1986;24:67-74.

மோரிஸ்கியின் நோயாளிகள் தவறாமல் மருந்துகளை சாப்பிடுகிறார்களா என்பதற்கான 8 விதமான கேள்விகள்

வ.எண்	கேள்விகள்	நோயாளியின் பதில்கள்	மதிப்பெண்கள் ஆம் = 1 இல்லை = 0
1	நீங்கள் எப்போதாவது மாத்திரைகளை எடுப்பதற்கு மறந்து விடுவீர்களா?	ஆம் / இல்லை	
2	மறதி இல்லாமல் வேறு வேலை காரணமாக மாத்திரை எடுக்காமல் விட்டு இருக்கிறீர்களா? கடந்த இரண்டு வாரங்களில் மாத்திரை எடுக்காமல் எத்தனை நாட்கள் விட்டுவிட்டீர்கள்?	ஆம் / இல்லை	
3	நீங்கள் எப்போதாவது பிரச்சனைகள் அதிகமாகிறது என நினைத்து மருத்துவரிடம் சொல்லாமல் மாத்திரைகளை நிறுத்தி இருக்கிறீர்களா?	ஆம் / இல்லை	
4	நீங்கள் வீட்டை விட்டு வெளியில் பயணம் செய்யும்போது மருந்துகளை எடுக்க மறந்து இருக்கிறீர்களா?	ஆம் / இல்லை	
5	நேற்று நீங்கள் அனைத்து மாத்திரைகளையும் சாப்பிட்டீர்களா?	ஆம் / இல்லை	
6	உங்கள் பிரச்சனைகள் கட்டுப்பாட்டிற்குள் இருக்கிறது என்று மருந்துகளை நீங்களாகவே நிறுத்தியதுண்டா?	ஆம் / இல்லை	
7	தினமும் மாத்திரைகளை எடுப்பது ஒரு சிலர் தொந்திரவாக இருப்பதாக நினைக்கிறார்கள். அப்படி நீங்களும் தினமும் மாத்திரைகளை சாப்பிடுவது தொந்திரவாக இருக்கிறது என்று நினைத்ததுண்டா?	ஆம் / இல்லை	
8	எல்லா மாத்திரைகளையும் ஞாபக்படுத்தி எடுப்பதற்கு நீங்கள் எத்தனைமுறை சிரமப்பட்டிருக்கிறீர்கள்?	i. எப்பொழுதும் இல்லை / எப்பொழுதாவது ii. எப்பொழுதாவது ஒருமுறை iii.ஒருசில நேரங்களில் iv.சாதாரணமாக v.எப்பொழுதும்	

Name of Patient: _____ Date form filled out:_____

Child's Sleep Habits Questionnaire (pre-school and school-aged children)

The following statements are about your child's sleep habits and possible difficulties with sleep. Think about the past week in your child's life when answering the questions. If last week was unusual for a specific reason (such as your child had an ear infection and did not sleep well or the TV set was broken) choose the most recent typical week.

Answer USUALLY if something occurs **5 or more times** in a week.

Answer SOMETIMES if it occurs **2-4 times** in a week.

Answer RARELY if something occurs **never or 1 time** during a week.

Indicate whether or not the sleep habit is a problem by circling "Yes", "No," or "not applicable (N/A)".

Write in child's bedtime: _____ Write in child's usual wake time: _____

Child's usual amount of sleep each night (no naps): _____hours and _____minutes

Child's usual amount of sleep each day (naps): _____hours and _____minutes 1	2 Sometimes (2-4)	3 Rarely (0-1)	Problem?
Usually (5-7)			
1. Child goes to bed at the same time at night	□	□	Yes No N/A
2. Child falls asleep alone in own bed	□	□	Yes No N/A
3. Child falls asleep within 20 minutes after going to bed	□	□	Yes No N/A
4. Child sleeps the right amount	□	□	Yes No N/A
5. Child sleeps about the same amount each day	□	□	Yes No N/A
6. Child wakes up by him/herself	□	□	Yes No N/A

PLEASE TURN OVER AND COMPLETE OTHER SIDE!!! Page 1 of 2

Name of Patient: _____ Date form filled out:_____

	3 Usually 5-7)	2 Sometimes (2-4)	1 Rarely (0-1)	Problem?
9. Child falls asleep in parent's or sibling's bed	☐	☐	☐	Yes No N/A
10. Child struggles at bedtime (cries, refuses to stay in bed, etc.)	☐	☐	☐	Yes No N/A
11. Child needs parent in the room to fall asleep	☐	☐	☐	Yes No N/A
12. Child is afraid of sleeping alone	☐	☐	☐	Yes No N/A
13. Child sleeps too little	☐	☐	☐	Yes No N/A
14. Child is afraid of sleeping in the dark	☐	☐	☐	Yes No N/A
15. Child has trouble sleeping away from home (visiting relatives, vacation)	☐	☐	☐	Yes No N/A
16. Child moves to someone else's bed during the night (parent, sibling, etc.)				
17. Child awakens once during the night	☐	☐	☐	Yes No N/A
18. Child awakens more than once during the night	☐	☐	☐	Yes No N/A
Write the number of minutes a night waking usually lasts: _____				
19. Child talks during sleep	☐	☐	☐	Yes No N/A
20. Child is restless and moves a lot during sleep	☐	☐	☐	Yes No N/A
21. Child sleepwalks during the night	☐	☐	☐	Yes No N/A
22. Child wets the bed at night	☐	☐	☐	Yes No N/A
23. Child grind teeth during sleep (your dentist may have told you this)	☐	☐	☐	Yes No N/A
24. Child awakens alarmed by a frightening dream	☐	☐	☐	Yes No N/A
25. Child awakens during night screaming,	☐	☐	☐	Yes No N/A

sweating, and inconsolable				
26. Child snores loudly	☐	☐	☐	Yes No N/A
27. Child seems to stop breathing during sleep	☐	☐	☐	Yes No N/A
28. Child snorts and/or gasps during sleep	☐	☐	☐	Yes No N/A
29. Child wakes up in a negative mood	☐	☐	☐	Yes No N/A
30. Adults or siblings wake up child	☐	☐	☐	Yes No N/A
31. Child has difficulty getting out of bed in the morning	☐	☐	☐	Yes No N/A
32. Child takes a long time to become alert in the morning	☐	☐	☐	Yes No N/A
33. Child seems tired in the morning	☐	☐	☐	Yes No N/A

குழந்தையின் தூங்கும் பழக்கம் பற்றிய கேள்வித்தாள்
(பள்ளி வயதிற்கு முன் மற்றும் பள்ளி வயது குழந்தைகள்)

பின்வரும் அறிக்கைகள் உங்கள் குழந்தையின் தூங்கும் பழக்கம் மற்றும் தூங்குவதற்குள்ள சிரமங்கள் பற்றியவை. கேள்விகளுக்கு பதிலை உங்கள் குழந்தைக்கு கடந்த வாரத்தில் நிகழ்ந்தவைகளாக இருக்க வேண்டும். ஒருவேளை கடந்த வாரம் சற்று வழக்கத்திற்கு மாறான வாரமாக இருந்தால், (உதாரணமாக குழந்தைக்கு காது வலியால் சரியாக தூங்கவில்லை அல்லது தொலைகாட்சி பெட்டி உடைந்த விட்டது போன்றவை) வழக்கமாக இருக்கக்கூடிய சமீப வார நிகழ்வாக தெரிவு செய்யவும்.

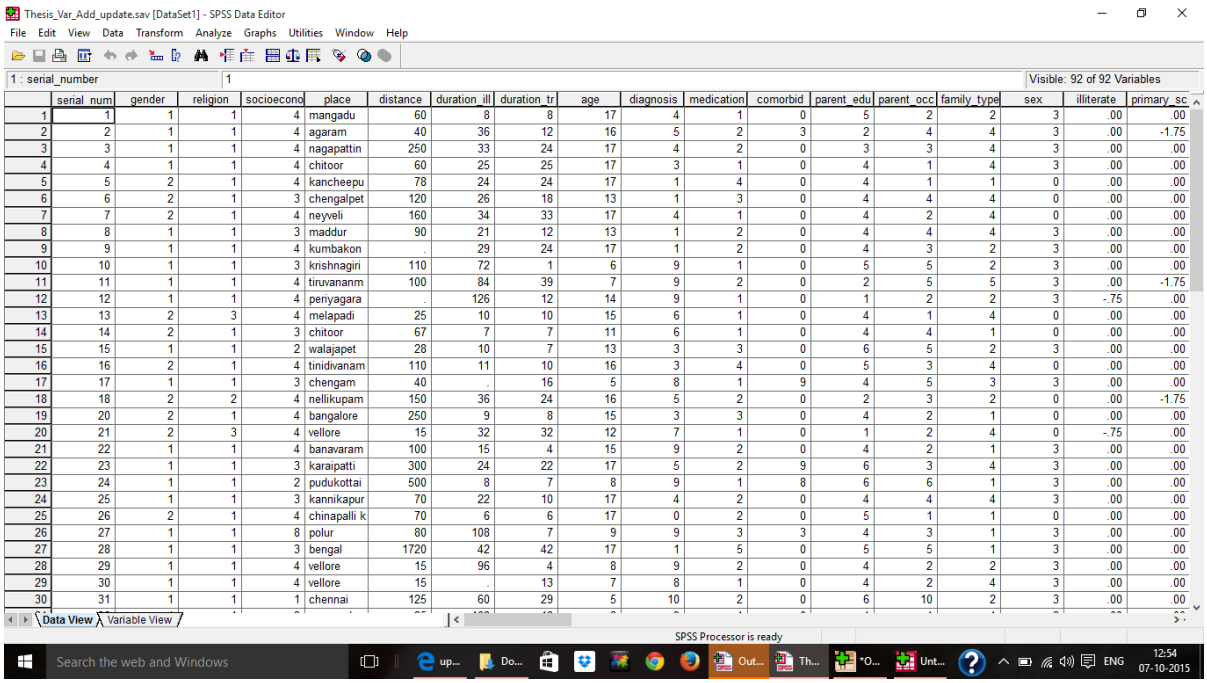
பதில்கள்:
1. வழக்கமாக ஒரு வாரத்தில் 5 அல்லது அதற்குமேல்
2. சில நேரங்களில் ஒரு வாரத்தில் 2 முதல் 4 முறை வரையில்
3. எப்போதாவது ஒருமுறை
தூங்குவதில் பிரச்சைக்கு உள்ளதா என்பதை குறிப்பிட "ஆம்" "இல்லை" அல்லது "பொருந்தாது" என குறிப்பிடவும்.

குழந்தை படுக்கைக்கு செல்லும் நேரத்தை எழுதவும்: _____ குழந்தை தூங்கி எழும் நேரத்தை எழுதவும்: _____
குழந்தை வழக்கமாக இரவில் தூங்கும் நேரம்: _____ மணி _____நிமிடங்கள்
குழந்தை வழக்கமாக ஒரு நாளில் தூங்கும் நேரம்: _____ மணி _____நிமிடங்கள்

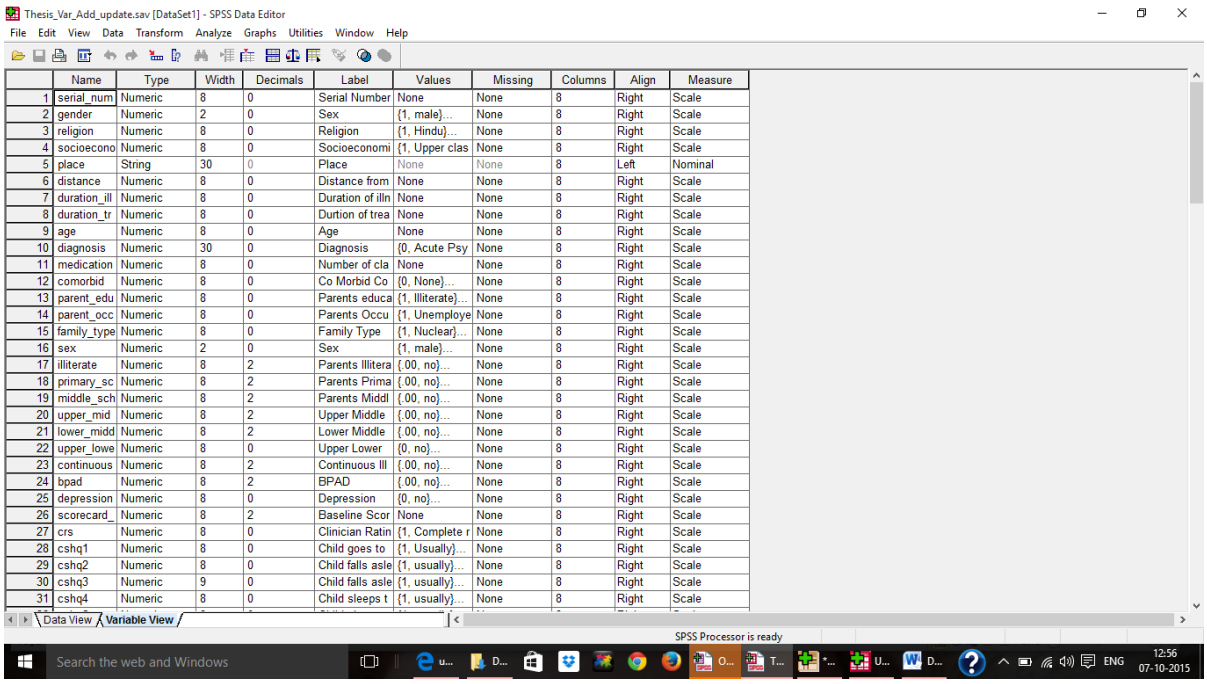
	கீழே குறிப்பிடப்பட்டுள்ள நேரங்களில் குழந்தை எவ்வாறு இருக்கும் என்பதை குறிப்பிடவும். (அனைத்தையும் சரி பார்க்கவும்)	1 வழக்கமாக (5 – 7)	2 சில நேரங்களில் (2 – 4)	3 எப்போதாவது (0 – 1)	பிரச்சனைகள் ஆம்	இல்லை	பொருந்தாது
1	குழந்தை இரவில் குறிப்பிட்ட நேரத்தில் படுக்கைக்கு சென்று விடும்						
2	குழந்தை தானாகவே தன்னுடைய படுக்கைக்கு சென்று விடும்						
3	குழந்தை படுக்கைக்கு சென்ற 20 நிமிடங்களில் ஆழ்ந்து தூங்கிவிடும்						
4	குழந்தை சரியான அளவு தூங்கும் நேரம்						
5	குழந்தை ஒவ்வொரு நாளும் சராசரியாக தூங்கும் நேரத்தின் அளவு						
6	குழந்தை தூக்கத்திலிருந்து தாமாகவே எழுந்துகொள்ளும்						
	கீழே குறிப்பிடப்பட்டுள்ள நேரங்களில் உங்கள் குழந்தை எப்படி நடந்து கொள்ளும் என்பதை குறிப்பிடவும். (அனைத்தையும் சரிபார்க்கவும்)	0 தூங்காமல் இருப்பது	1 மிகவும் தூக்க கலக்கத்தில் இருப்பது	2 ஆழ்ந்து தூங்கி விடுவது			

7	தொலைகாட்சி பார்த்துக்கொண்டிருக்கும்போது						
8	காரில் பயணம் செய்யும்போது						
		3 வழக்கமாக (5 – 7)	2 சில நேரங்களில் (2 – 4)	1 எப்போதாவது (0 – 1)			
9	குழந்தை பெற்றோர் அல்லது உறவினர் படுக்கையில் தான் தூங்கும்						
10	குழந்தை படுக்கையில் தூக்கத்திற்காக போராடுகிறது (அழுவது, படுபதற்கு மறுப்பது, போன்றவை)						
11	குழந்தை தூங்கும்போது பெற்றோர் உடனியிருக்க வேண்டும்						
12	குழந்தை தனிமையில் தூங்குவதற்கு பயப்படும்						
13	குழந்தை தூங்கும் நேரம் மிகவும் குறைவு						
14	குழந்தை இருட்டில் தூங்குவதற்கு பயப்படும்						
15	குழந்தை வேற்று (அ) புதிய இடங்களில் தூங்குவதற்கு கஷ்டப்படும் (உறவினர்கள் மற்றும் விடுமுறையில் வெளி இடங்களுக்கு காணச்செல்லும் போது)						
16	குழந்தை தூங்கும்போது வேறொருவர் படுக்கைக்கு சென்றுவிடும் (பெற்றோர் அல்லது உறவினர்)						
17	குழந்தை இரவில் ஒருமுறை விழித்துக்கொள்ளும்						
18	குழந்தை இரவில் அடிக்கடி விழித்துக்கொள்ளும் (எவ்வளவு நேரம் என்பதை எழுதவும்_____)						
19	குழந்தை தூக்கத்தில் பேசுவது						
20	குழந்தை தூங்கும்போது மிகவும் அமைதியற்று இப்படியும் அப்படியுமாக இருப்பது						
21	குழந்தை தூக்கத்தில் நடப்பது						
22	குழந்தை தூக்கத்தில் படுக்கையை நனைத்துவிடுவது						
23	குழந்தை தூக்கத்தில் பற்களை கடிப்பது (உங்கள் பல் மருத்துவர் இதுபற்றி சொல்லியிருப்பார்)						
24	குழந்தை தூக்கத்தில் கனவு கண்டு பயந்து அலறி எழுவது						

25	குழந்தை தூக்கத்தில் அலறி, வியர்வையுடன், அமைதியற்று எழுந்தபின் அமைதிபடுத்துவது கடினம்						
26	குழந்தை தூங்கும்போது சத்தமாக குறட்டை விடுதல்						
27	குழந்தை தூங்கும்போது மூச்சுவிடுவதை நிறுத்தி விட்டது போலிருத்தல்						
28	குழந்தை ஒருவகையான மூச்சுத்தினறல் அடைவது						
29	குழந்தை எதிர்மறை மனநிலையுடன் விழித்துக்கொள்ளுதல்						
30	குழந்தையை பெரியவர்கள் அல்லது உறவினர் தான் எழுப்பவேண்டும்						
31	குழந்தை காலையில் எழுந்துகொள்வதில் சிரமப்படுவது						
32	குழந்தை தூங்கி எழுந்த பிறகு தெளிவடைவதற்கு வெகு நேரம் எடுப்பது						
33	குழந்தை காலையில் மிகவும் சோர்வாக இருப்பது						



	serial_num	gender	religion	socioecono	place	distance	duration_ill	duration_tr	age	diagnosis	medication	comorbid	parent_edu	parent_occ	family_type	sex	illiterate	primary_sc
1	1	1	1	4	mangadu	60	8	8	17	4	1	0	5	2	2	3	.00	.00
2	2	1	1	4	agaram	40	36	12	16	5	2	3	2	4	4	3	.00	-1.75
3	3	1	1	4	nagapattin	250	33	24	17	4	2	0	3	3	4	3	.00	.00
4	4	1	1	4	chitoor	60	25	25	17	3	1	0	4	1	4	3	.00	.00
5	5	2	1	4	kancheepu	78	24	24	17	1	4	0	4	1	1	0	.00	.00
6	6	2	1	3	chengalpet	120	26	18	13	1	3	0	4	4	4	0	.00	.00
7	7	2	1	4	neyveli	160	34	33	17	4	1	0	4	2	4	0	.00	.00
8	8	1	1	3	maddur	90	21	12	13	1	2	0	4	4	4	3	.00	.00
9	9	1	1	4	kumbakon	.	29	24	17	1	2	0	4	3	2	3	.00	.00
10	10	1	1	3	krishnagiri	110	72	1	6	9	1	0	5	5	2	3	.00	.00
11	11	1	1	4	tiruvananm	100	84	39	7	9	2	0	2	5	5	3	.00	-1.75
12	12	1	1	4	periyagara	.	126	12	14	9	1	0	1	2	2	3	-.75	.00
13	13	2	3	4	melapadi	25	10	10	15	6	1	0	4	1	4	0	.00	.00
14	14	2	1	3	chitoor	67	7	7	11	6	1	0	4	4	1	0	.00	.00
15	15	1	1	2	walajapet	28	10	7	13	3	3	0	6	5	2	3	.00	.00
16	16	2	1	4	tinidivanam	110	11	10	16	3	4	0	5	3	4	0	.00	.00
17	17	1	1	3	chengam	40	.	16	5	8	1	9	4	5	3	3	.00	.00
18	18	2	2	4	nellikupam	150	36	24	16	5	2	0	2	3	2	0	.00	-1.75
19	20	2	1	4	bangalore	250	9	8	15	3	3	0	4	2	1	0	.00	.00
20	21	2	3	4	vellore	15	32	32	12	7	1	0	1	2	4	0	-.75	.00
21	22	1	1	4	banavaram	100	15	4	15	9	2	0	4	2	1	3	.00	.00
22	23	1	1	3	karaipatti	300	24	22	17	5	2	9	6	3	4	3	.00	.00
23	24	1	1	2	pudukottai	500	8	7	8	9	1	8	6	6	1	3	.00	.00
24	25	1	1	3	kannikapur	70	22	10	17	4	2	0	4	4	4	3	.00	.00
25	26	2	1	4	chinapalli k	70	6	6	17	0	2	0	5	1	1	0	.00	.00
26	27	1	1	8	polur	80	108	7	9	9	3	3	4	3	1	3	.00	.00
27	28	1	1	3	bengal	1720	42	42	17	1	5	0	5	5	1	3	.00	.00
28	29	1	1	4	vellore	15	96	4	8	9	2	0	4	2	2	3	.00	.00
29	30	1	1	4	vellore	15	.	13	7	8	1	0	4	2	4	3	.00	.00
30	31	1	1	1	chennai	125	60	29	5	10	2	0	6	10	2	3	.00	.00



	Name	Type	Width	Decimals	Label	Values	Missing	Columns	Align	Measure
1	serial_num	Numeric	8	0	Serial Number	None	None	8	Right	Scale
2	gender	Numeric	2	0	Sex	{1, male}...	None	8	Right	Scale
3	religion	Numeric	8	0	Religion	{1, Hindu}...	None	8	Right	Scale
4	socioecono	Numeric	8	0	Socioeconomi	{1, Upper clas	None	8	Right	Scale
5	place	String	30	0	Place	None	None	8	Left	Nominal
6	distance	Numeric	8	0	Distance from	None	None	8	Right	Scale
7	duration_ill	Numeric	8	0	Duration of illn	None	None	8	Right	Scale
8	duration_tr	Numeric	8	0	Durtion of trea	None	None	8	Right	Scale
9	age	Numeric	8	0	Age	None	None	8	Right	Scale
10	diagnosis	Numeric	30	0	Diagnosis	{0, Acute Psy	None	8	Right	Scale
11	medication	Numeric	8	0	Number of cla	None	None	8	Right	Scale
12	comorbid	Numeric	8	0	Co Morbid Co	{0, None}...	None	8	Right	Scale
13	parent_edu	Numeric	8	0	Parents educa	{1, Illiterate}...	None	8	Right	Scale
14	parent_occ	Numeric	8	0	Parents Occu	{1, Unemploye	None	8	Right	Scale
15	family_type	Numeric	8	0	Family Type	{1, Nuclear}...	None	8	Right	Scale
16	sex	Numeric	2	0	Sex	{1, male}...	None	8	Right	Scale
17	illiterate	Numeric	8	2	Parents Illitera	{.00, no}...	None	8	Right	Scale
18	primary_sc	Numeric	8	2	Parents Prima	{.00, no}...	None	8	Right	Scale
19	middle_sch	Numeric	8	2	Parents Middl	{.00, no}...	None	8	Right	Scale
20	upper_mid	Numeric	8	2	Upper Middle	{.00, no}...	None	8	Right	Scale
21	lower_midd	Numeric	8	2	Lower Middle	{.00, no}...	None	8	Right	Scale
22	upper_lowe	Numeric	8	0	Upper Lower	{0, no}...	None	8	Right	Scale
23	continuous	Numeric	8	2	Continuous Ill	{.00, no}...	None	8	Right	Scale
24	bpad	Numeric	8	2	BPAD	{.00, no}...	None	8	Right	Scale
25	depression	Numeric	8	0	Depression	{0, no}...	None	8	Right	Scale
26	scorecard_	Numeric	8	2	Baseline Scor	None	None	8	Right	Scale
27	crs	Numeric	8	0	Clinician Ratin	{1, Complete r	None	8	Right	Scale
28	cshq1	Numeric	8	0	Child goes to	{1, Usually}...	None	8	Right	Scale
29	cshq2	Numeric	8	0	Child falls asle	{1, usually}...	None	8	Right	Scale
30	cshq3	Numeric	9	0	Child falls asle	{1, usually}...	None	8	Right	Scale
31	cshq4	Numeric	8	0	Child sleeps t	{1, usually}...	None	8	Right	Scale