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IMPACT OF REMINDER ON MEDICATION ADHERENCE: A STRUCTURAL EQUATION MODEL, BASED ON STUDY IN SIKKIM, INDIA

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Abstract

The problem of medication non-adherence has persisted over decades. The rate of adherence decreases with time and improvement in health condition. When patients cannot follow their prescribed medication regime, it leads to deterioration of their health condition and increases their financial costs. This research aims to find the effect of reminder on medication adherence behaviour of patients when "Acceptance of Side Effect", "Quality of Life" and "Medication Beliefs" act as mediators. The sample size of the research was 505. Sampling units comprised patients suffering from different diseases in Central Referral Hospital, Sikkim, India. By developing a Structural Equation Model, the effect of reminder on the mediators and adherence was analysed. The results show a significant positive association between reminder and the three mediators. Reminder has a significant positive effect on adherence (β=0.637, e=0.055, p=0.001). The effect is higher in the presence of mediators (β=0.7, e=0.037, p=0.001).

Keywords: Belief. Medication Adherence. Perception. Physician Advice. Reminder. Side Effect.

1. Introduction

Medication non-adherence is common with patients. Proper medication compliance helps to avert complications and reduce health care costs (Ranjbaran et al. 2020). Reminders as SMS, mobile apps and packaging rendered overall high satisfaction among patients (Park et al. 2014). Interventions help to convey educational information to health professionals, patients, and their family. Data collection, diagnosis, and monitoring of patient health enhance with the usage of technology (Santo et al. 2017). 30 to 50% of patients suffering from chronic diseases resort to non-adherence (Naderi et al. 2012). Intervention techniques such as pharmacist-led multidisciplinary cooperation and education, formulary restrictions, motivational interviewing showed improvement in adherence (Zomahoun et al. 2017). Technology-based interventions such as alarms, mobile applications, the internet and television have increased adherence (Choudhry et al. 2017). Theories of health behaviour change help to decide, describe, and promote the self-regulation of individuals and to optimize treatment (Dunn and Elliott 2008).

The behaviour of medication adherence is complex. Its true cause-and-effect relationship is hard to decipher. Factors such as depression, stage and severity of disease, family, social support, lifestyle, medication beliefs, side effects, perception of side effects affect the adherence behaviour of patients (Mols et al. 2020). Although reminders are effective in enhancing the adherence rates, limited literature exists on the effect of reminders on factors related to adherence and their joint effect on adherence. Hence, this research aims to find the effect of reminder on medication adherence behaviour of patients when

"Acceptance of Side Effect", "Quality of Life" and "Medication Beliefs" act as mediators. Figure 1 is the proposed model for the study.

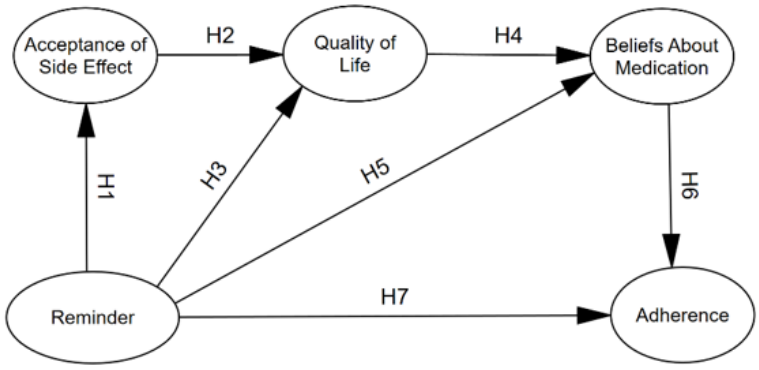

Figure 1. Conceptual model and hypotheses.

- Hypothesis H1: "Reminder" has a positive and significant effect on "Acceptance of Side Effect".
- Hypothesis H2: "Acceptance of Side Effect" has a positive and significant effect on "Quality of Life".

Medicines often have side effects. Adherence decrease as the side effects become more pronounced. Interventions help to "minimize or manage medication side effects" (Lachs and Han 2015). Factors such as disease severity, perception, family support and counselling determine continuity of medication in the presence of side effect (Ward et al. 2020). "Acceptance of Side Effect" passively affects the adherence rate. Hence, it is postulated that "Reminder" will affect the patient's "Acceptance of Side Effect" which will affect the "Quality of Life".

- Hypothesis H3: "Reminder" has a positive and significant effect on "Quality of Life".
- Hypothesis H4: "Quality of Life" has a positive and significant effect on "Beliefs about Medication".

According to the literature, patients with poor perception about "Quality of Life" have poor "Medication Beliefs" (Hall et al. 2007). Hence, we postulate that "Reminder" will affect the patient's perception about "Quality of Life". "Reminder" will have a mediating effect on "Quality of Life" through "Acceptance of Side Effect". The combined effect will affect the "Medication Beliefs".

- Hypothesis H5: "Reminder" has a positive and significant effect on "Medication Beliefs".
- Hypothesis H6: "Medication Beliefs" has a positive and significant effect on "Adherence".
- Hypothesis H7: "Reminder" has a positive and significant effect on "Adherence".

Patients who give more importance to their physician's instruction have better adherence (Lin et al. 2020). Their "Medication Beliefs" affect adherence (Salama and Saudi 2020). Interventions should target "Medication Beliefs" to improve adherence (Qiao et al. 2020). In this study, it is postulated that patient's "Quality of Life" and "Reminder" affect "Medication Beliefs". The effect of mediation from "Reminder" to "Acceptance of Side Effect" and "Reminder" to "Quality of Life" affects the "Medication Beliefs". Hence, it is postulated that the sum of all these effects changes the medication adherence behaviour of patients.

2. Material and Methods

Patient inclusion criteria

The study was conducted on patients possessing a mobile phone, living in Sikkim, and who had been prescribed medication for over three months by a medically qualified practitioner. However, seriously ill patients who required treatment based on hospitalization were excluded from the study.

Patient recruitment

Patients of Central Referral Hospital, Tadong, Sikkim who fulfilled the above inclusion criteria were recruited for the study. Patients who agreed to take part in the study gave their consent by signing a written consent form. Written permission was taken from the Hospital Superintendent for conducting the survey. All recruited patients were informed about the study objectives and their signatures were taken in a written consent form.

Study design

Patients were given reminders at five different levels. The first level had no reminder which served as the control group. The second-level reminder was for a week. Third-level reminder comprised one alarm in the morning. Fourth-level reminder comprised two alarms in a day (morning and evening). For the fifth level, a reminder was set before every dose. Survey for level one was conducted first. For the other levels, a survey was conducted after three months.

Data collection period

August 2019 to September 2020.

Instrument used for data collection

A survey was conducted with the help of a structured questionnaire. For each of the latent constructs identified for the study, few variables were identified and questions were framed on a 10-point scale (1 being lowest and 10 being highest). A brief description of the variables is given in table 1. Five experts validated these questions in terms of face validity, appropriateness, clarity, objectivity and relevance. BMQ was used for measuring adherence (Svarstad et al. 1999). Permission was taken for use of BMQ from its developers. The questions for measuring adherence were attuned, as per the study.

Determination of sample size is critical in SEM analysis. A large sample size helps to improve the trustworthiness and statistical power of results. Depending on the value of communality and model complexity of SEM, the minimum sample size differs. Since there are 5 constructs in the model, a sample size greater than 50 + (5*K) (where K is the number of constructs) = 50 + (5*5) = 300 was tried to achieve. Hence, to have a sufficient sample size, 525 patients were interviewed. Out of this, 11 responses were removed because of missing values (data collection error). 9 responses were removed as their Mahalanobis distance was greater than 50. Therefore, the final sample size was 505, which is more than the minimum sample size required for SEM analysis with 5 constructs.

Exploratory Factor Analysis (EFA) was conducted using SPSS version 26. The variable screening was done using Skewness and Kurtosis. A collinearity test was done with tolerance and Variance Inflation Factor (VIF) analysis. Constructs were formed based on the factors of EFA. Using these constructs, Confirmatory Factor Analysis (CFA) and path analysis was conducted in AMOS version 26.

3. Results

Sample characteristics

61% of the respondents were male and 39% female. 22% of respondents had education up to school level, and 39% up to graduation and masters each. 37% of the respondents had a per month income of less than US$340, 25% between US$340 and US$680, 17% between US$680 and US$1020 and 22% above US$1020.

Validity and reliability of the variables

As depicted in Table 1, Skewness and Kurtosis values ranged around ± 1 for most of the variables. For the variable “I1” the value of Kurtosis was above 3. Because of its importance, the variable was kept. The assumption of collinearity was not violated as the values of variables were within the limits for tolerance (>0.01) and VIF (<10).

Table 1. Variables and their statistics.

Latent Variables	Variables	Description	Skewness	Kurtosis	Collinearity Statistics	
Beliefs about Medication	I1	Importance of following medication timing	-1.616	3.255	0.665	1.503
	I2	Importance of following Physician's instructions	-1.246	1.324	0.599	1.670
	I3	Importance of following diet as prescribed by Physician	-1.208	1.448	0.589	1.699
Quality of Life	B1	Importance of following proper medication regime so as not to make one bed ridden	-0.961	0.96	0.581	1.723
	B2	Importance of following proper medication regime so that one's responsibilities can be fulfilled	-1.13	1.235	0.364	2.747
	B3	Importance of following proper medication regime so that one remains self-dependent	-1.114	1.114	0.398	2.514
Acceptance of Side Effect	SE1	Importance of continuing medication even if it causes tiredness	-0.204	-1.015	0.384	2.605
	SE2	Importance of continuing medication even if it leads to gas formation	-0.117	-1.115	0.226	4.416
	SE3	Importance of continuing medication even if it leads to upset stomach	0.051	-1.171	0.164	6.090
	SE4	Importance of continuing medication even if it leads to formation of rashes	0.398	-1.117	0.331	3.020
Adherence	A1	Forgot to take medication completely	-0.466	0.11	0.668	1.498
	A2	How many times medicine is missed in a week?	-0.246	-0.968	0.514	1.947
	A3	By how much time one defers from the scheduled time of medicine	-0.392	-0.418	0.444	2.250
Reminder	RE1	Use of alarm as a form of reminder	-0.012	-1.584	0.419	2.385
	RE2	Use of mobile as a form of reminder	0.306	-1.502	0.553	1.808

Exploratory factor analysis (EFA)

The Principal Components method with Varimax rotation was used to get the factors. Kaiser-Meyer-Olkin Measure of Sampling Adequacy was 0.811 and Bartlett's Test of Sphericity was significant (0.000). As shown in Table 2, all the constructs are reliable since Cronbach's Alpha for all the variables are above 0.7 and the value of overall Cronbach's Alpha being 0.803. The extraction score of commonalities for all the variables was also above 0.5. Since the cumulative total variance explained was 76.097% and variance for none of the constructs too high, we can say that variance explained by each of the constructs was meaningful. Factor loadings above 0.5 show convergent validity. Similarly, no strong cross-loadings between the variables confirmed discriminant validity. The total variance explained in Harman's one-factor test was 24.337%, which is below 50%. Hence, there is no common method bias.

Table 2. Validity of EFA.

Factors	Cronbach's Alpha	Rotation Sums of Squared Loadings	
		% of Variance	Cumulative %
Acceptance of Side Effect	0.922	21.800	21.800
Quality of Life	0.846	15.450	37.250
Adherence	0.78	15.220	52.470
Beliefs about Medication	0.749	13.797	66.267
Reminder	0.791	9.830	76.097

Confirmatory factor analysis (CFA)

Based on the factors got from EFA, constructs were formed (shown in Table 2). In CFA latent variables are used because they help to increase the common-to-unique ratio for each indicator. They also enhance scale commonality, reduce random error, improve model efficiency, increasing reliability with stable parameter estimation. Factor loading of every indicator was found to be greater than the threshold value of 0.5 and significantly related to the construct at $p < 0.001$. The Maximum Likelihood method was used in AMOS 26 to analyse both the measurement and structural models. The correlation between the error terms "e2" and "e3" (as shown in Figure 2) was high. Hence, they were correlated to enhance the model fitness.

Table 3. Validity of CFA.

Constructs	CR	AVE	MSV	MaxR(H)	Acceptance of Side Effect	Adherence	Beliefs about Medication	Quality of Life	Reminder
Acceptance of Side Effect	0.919	0.741	0.033	0.980	0.861				
Adherence	0.795	0.568	0.493	0.828	0.062	0.753			
Beliefs about Medication	0.756	0.509	0.255	0.760	0.111*	0.447***	0.713		
Quality of Life	0.852	0.660	0.142	0.884	0.181***	0.187***	0.376***	0.812	
Reminder	0.809	0.685	0.493	0.898	0.131**	0.702***	0.505***	0.218***	0.827

Significance of Correlations: † $p < 0.100$, * $p < 0.050$, ** $p < 0.010$, *** $p < 0.001$.

The Composite Reliability (CR) of all the constructs were above 0.7 (as shown in Table 3), Average Variance Extracted (AVE) was above 0.5 and individual Maximum Shared Variance (MSV) was less than the Maximal Reliability (MaxR (H)). Hence, no validity concerns were reported for the model. Divergent validity (which ensures the uniqueness of each construct) was ensured, as none of the covariances between the constructs was above 0.85. Also, every construct's AVE was greater than the square correlation between constructs (as shown in Table 3) which confirmed divergent validity. Since all the validity and reliability conditions of the CFA–measurement model was satisfied, the structural model was framed as per the theorized model as shown in Figure 1, and the different paths were analysed regarding estimates and p-value (shown in Table 4).

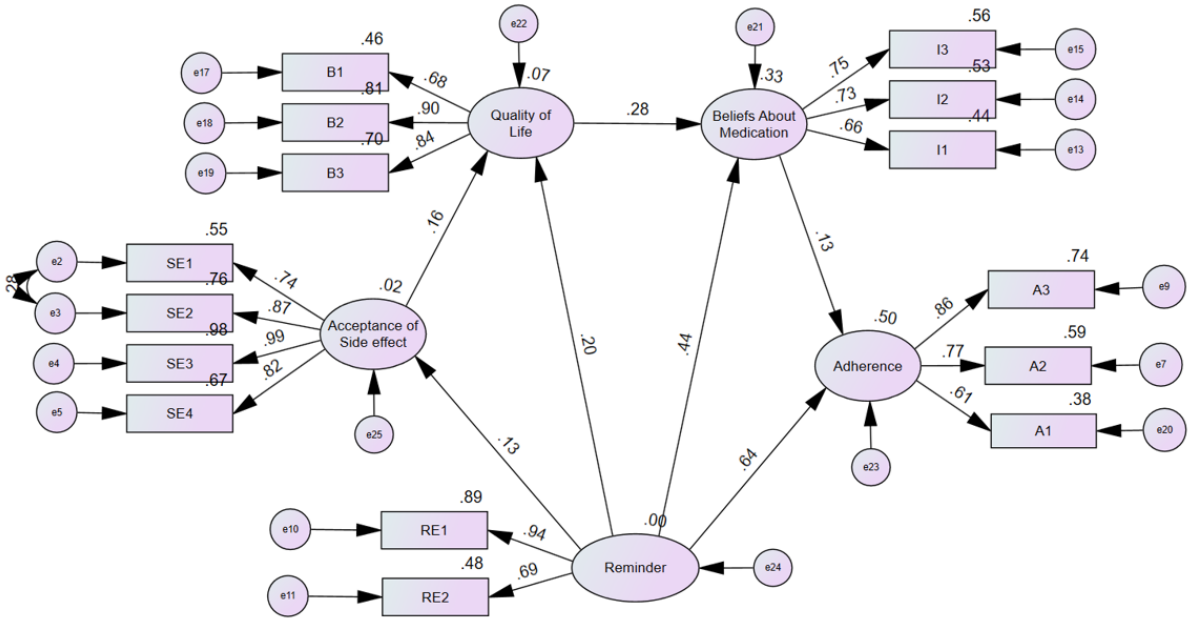

Figure 2. Structural model.

The global model fit indices of the structural and measurement model (shown in Figure 2) were adequate. For the measurement model, all the indices were above 0.9. The value of Goodness of Fit Index (GFI) was 0.972, Aggregate Goodness of Fit Index (AGFI) was 0.952, Tucker-Lews index (TLI) was 0.990, and Comparative Fit Index (CFI) was 0.992. The badness of fit indices was also adequate as the values of Root Mean Square Error of Approximation (RMSEA) were 0.027 and PCLOSE 1.000. The local model fit indices were significant for the regression weights, and intercepts for all the variables. As the paths of the structural model are significant at a 95% confidence level, the conceptual model can be accepted. The constructs, "Reminder", "Acceptance of Side Effect", "Quality of Life", and "Medication Beliefs" together explain 50% variance in "Adherence". It means that the constructs are relevant factors in enhancing "Adherence".

To find out the direct, indirect, and total effects, a bootstrap standard error-based test with 2000 samples at 95% Bias-Corrected Confidence interval was done. The estimates of direct and total effects with their corresponding p-values are shown in Table 4. The paths are significant (p-value < 0.05) at a 95% confidence level. However, the direct and total effect of the construct "Medication Beliefs" on "Adherence" is significant only at a 90% confidence level.

Table 4. Path Analysis with Direct and Total Effects – goes here.

	Direct Effects Estimates (p-value)				Total Effects Estimates (p-value)			
	Reminder	Acceptance of Side effect	Quality of Life	Beliefs About Medication	Reminder	Acceptance of Side effect	Quality of Life	Beliefs About Medication
Acceptance of Side effect	0.099 (0.012)	0	0	0	0.099 (0.012)	0	0	0
Quality of Life	0.104 (0.001)	0.106 (0.002)	0	0	0.115 (0.001)	0.106 (0.002)	0	0
Beliefs About Medication	0.136 (0)	0	0.162 (0.001)	0	0.154 (0)	0.017 (0.001)	0.162 (0.001)	0
Adherence	0.09 (0.001)	0	0	0.058 (0.073)	0.099 (0.001)	0.001 (0.024)	0.009 (0.049)	0.058 (0.073)

4. Discussion

Hypothesis H1

From the standardized path model, it was found that "Reminder" has a significant positive effect on "Acceptance of Side Effect" (β=0.128, e=0.048, p=0.012). Hence, hypothesis H1 is accepted. The result is as per the theorised model and published literature (Rodrigues et al. 2015). As patients increase the use of reminder, their "Acceptance of Side Effect" also increases. A study conducted in Malaysia reported that 17.8% of the patients recruited for the study did not adhere to their medication regime because of side effect. After introducing mobile application as an intervention technique, 52.2% of the respondents considered the side effect management tool of the app to be the most important feature (Abdullah et al. 2020).

Hypothesis H2

"Acceptance of Side Effect" has a significant positive effect on "Quality of Life" with standardized direct effect values β=0.156, e=0.051, p=0.002. Hence, hypothesis H2 is accepted. Patients' "Quality of Life" is affected by several factors (Williams et al. 2020). "Acceptance of Side Effect" helps a patient to enhance their perception about "Quality of Life". Patients with a positive attitude towards medication side effect will adhere to the medication regime despite the side effects. They wish to get the disease cured, lead a quality life, and fulfil their responsibilities. They do not want to depend on others or get bedridden. Studies conducted on breast cancer patients suggest psychological factors play a role in the prevention of side effects. It helps to improve their quality of life during long-term medication intake (Von Blanckenburg et al. 2013).

Hypothesis H3

"Reminder" has a significant positive effect on "Quality of Life". The values of standardized direct effect are β=0.198, e=0.051, p=0.001. Hence, hypothesis H3 is accepted. It is as per the theoretical model and the studies already conducted. It suggests that the use of reminder helps to enhance the patients' "Quality of Life". The values of standardized total effect are β=0.218, e=0.05, p=0.001. The β value increases as the effect of "Acceptance of Side Effect" also gets added to form the total effect. Hence, the total effect on "Quality of Life" due to "Reminder" is the sum of paths (H1 X H2) and (H3). Studies based on patients suffering from type 2 diabetes mellitus (Güner and Coşansu 2020), blood pressure (Zhang et al. 2020), Rheumatoid Arthritis (Thomsen et al. 2020) etc. have shown improvement in quality of life by the use of reminders. Reminders also help to prevent the intake of the wrong medicine dose (Rahimi et al. 2021).

Hypothesis H4

Patients "Medication Beliefs" is affected by several factors. Literature suggests that a person's "Quality of Life" helps to determine the patients "Medication Beliefs" (Piernavieja et al. 2020). On testing the hypothesis H4, it was found that "Quality of Life" has a significant positive effect on "Medication Beliefs" with standardized direct effect values: β=0.280, e=0.059, p=0.001. Hence, hypothesis H4 is accepted. It was found that indeed a patients' perception about "Quality of Life" affects the perception about following proper timing of medication, diet and physician's instruction. Studies conducted on patients with kidney transplant also report that medication beliefs affect the quality of life (Zelikovsky and Nelson 2021).

Hypothesis H5

"Reminder" has a significant positive effect on "Medication Beliefs". The values of standardized direct effect are β=0.443, e=0.049, p=0.001. Hence, hypothesis H5 is accepted. Studies show that "Reminders" helps to change patients' "Medication Beliefs" (Salama and Saudi 2020). From the SEM it was found that β value increases when the effect of "Acceptance of Side Effect" and "Quality of Life" is considered for calculating the total effect of "Reminder" on "Medication Beliefs". The values of standardized total effect are β=0.504, e=0.045, p=0.001. This is supported by a study that reports that interventions to improve

medication adherence and quality of life outcomes should focus on improving patients' negative beliefs (Thomson et al. 2020). The total effect is calculated as the sum of paths H5 and (((H1 x H2) + H3) X H4). A study on Dutch patients reveals that the group of patients who received intervention as a reminder had improved positive effect on medication beliefs than the control group (Kooy et al. 2014).

Hypothesis H6

Medication adherence behaviour of patients is complex, and many factors are associated with it. Published literature suggests that patients' "Medication Beliefs" plays a very important role in adhering to the medication regime (Tan et al. 2020). If patients believe that timing is not important, they will neglect the regime. If they believe that diet control is not important, they may resort to unhealthy food habits. Further, if they do not consider the physician's advice to be important, they may not follow the instructions properly. All these results in decreased adherence rates. In this study, it was found that "Medication Beliefs" has a significant positive effect on "Adherence" with standardized direct effect values: β=0.126, e=0.068, p=0.077. Hence, hypothesis H6 is accepted. Similar results were found in a study conducted with 246 patients suffering from co-morbid diabetes mellitus and hypertension. It was found that patients with positive medication beliefs and a higher degree of personal control had significantly welled rates of medication adherence (Christensen et al. 2010).

Hypothesis H7

"Reminder" has a significant positive effect on "Adherence". The values of standardized direct effect are β=0.637, e=0.055, p=0.001. Hence, hypothesis H7 is accepted. Literature suggests that the use of "Reminder" is directly proportional to the medication adherence rate (Liu and Varshney 2020). The values of standardized total effect are β=0.7, e=0.037, p=0.001. β value increased as the effect of "Acceptance of Side Effect", "Quality of Life" and "Medication Beliefs" are added to form the total effect of "Reminder" on "Adherence". Total effect is calculated as sum of paths (((((H1 x H2) + H3) X H4) + H5) x H6) and H7. Results were similar in diabetes mellitus studies (Ardianti et al. 2020) where patients showed significant improvement in diet, exercise, and medication intake when reminders were used. In another study, medication adherence improved from 59.9% at baseline to 81.3% for patients suffering from glaucoma when interventions were used (Newman-Casey et al. 2020). However, SMS reminders were ineffective in promoting PrEP adherence among young Kenyan women (Haberer et al. 2021). The meta-analysis of a systematic review involving 1,785 participants with 940 randomized to a mobile app intervention group showed that use of mobile apps had a significant improvement in patient adherence to medication (Cohen's d = 0.40, 95% CI = 0.27-0.52; P < 0.001) (Peng et al. 2020).

The effect of reminder on adherence is higher in the presence of mediators. Literature shows that patients concerned with the side effects or dependence liability had intentional non-adherence (Jimenez et al. 2017). Studies conducted with Chinese patients also report that adherence is directly proportional to the beliefs of patients (Cai et al. 2020). Intervention help patients understand their health condition and therapy. This causes a change in their beliefs and increases adherence (Magadza et al. 2009). As the standardized residual covariances are within acceptable limits, except for the variable "SE1", the model developed in this study can be generalized for the population at large. However, as the study was conducted in Sikkim, India, the perspective of people in other parts of the world could differ. During the interview, it was found that religious beliefs had a significant impact on adherence behaviour, which had not been included in the study. Hence, future research could take religious beliefs also into account. The study was done to find a holistic behaviour of adherence based on reminders. Future research could be directed towards specific disease or specific reminders.

Limitations

- The study was conducted for a specific population and was limited to patients living in Sikkim.
- The study was limited to the intervention of alarm and mobile app as forms of reminder.
- The effect of moderators has not been included in the study.

- The study is contemporary and the results may change with the adoption of reminders in the day-to-day activities or their automatic inclusion in the lifestyle of people or medication packaging, offerings, etc.

5. Conclusions

The aim of the study was to find the effect of reminder on medication adherence behaviour of patients when "Acceptance of Side Effect", "Quality of Life" and "Medication Beliefs" act as mediators. It was found that reminder has a significant effect on patients' perception about "Acceptance of Side Effect", "Quality of Life", "Beliefs about Medication" and "Adherence". The seven hypotheses framed for the model were significant and the path coefficients showed significant improvement in adherence when "Acceptance of Side Effect", "Quality of Life" and "Beliefs about Medication" acted as mediators.

Authors' Contributions: SAHA, S.K.: conception and design, acquisition of data, analysis and interpretation of data, drafting the article; JHA, A.: conception and design, drafting the article, critical review of important intellectual content. All authors have read and approved the final version of the manuscript.

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Ethics Approval: Approved by Sikkim Manipal Institute of Medical Sciences. Number: SMIMS/IEC/2018-064.

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