

Double blind, randomized, controlled study  
of a psychotherapy designed to improve  
motivation for change, insight into schizophrenia  
and adherence to medication.

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# Introduction

- Most patients with DSM-IV schizophrenia exhibit full or partial non-adherence to pharmacological treatment (Rummel-Kluge, 2008). Only about one-third reliably take antipsychotic medication as prescribed (Oehl, 2000). Partial compliance in schizophrenia starts within days of medication initiation and prevalence increase up to 25% within 7-10 days, up to 50% after a year and up to 75% after two years (Keith & Kane, 2003).
- Poor adherence (i.e., both complete and partial non adherence) has been found to be associated with serious negative outcomes and as such, interventions aimed at improving and maintaining adherence are of great interest to clinicians (Patel, 2008), researchers, and policy makers.

# Limitations in existing data

- To date, however, few studies have examined compliance rates based on reliable assessments : subjective and indirect methods including self-report, provider report, significant other report, and chart review were the only methods used to assess adherence in over 77% (124/161) of studies reviewed (Velligan et al., 2006).
- Characterizing the types of psychological factors that increase risk for non compliance in schizophrenia may help identify the need for therapeutic interventions. This may be particularly important with patients newly diagnosed with Schizophrenia or following the medication initiation.

# Purpose

- In this study, we assess the efficacy of a psychotherapy based on motivational enhancement and cognitive therapies designed to improve patient's adherence to treatment and motivation to change (Listen-Empathize-Agree-Partner, or LEAP therapy; Amador, 2007).

# Methods

## METHODS

- 54 patients diagnosed with schizophrenia about to be discharged following inpatient treatment were included in a six month repeated measures study. Patients were randomly assigned to either the experimental or control therapies and were blind to group assignment.
- All patients received long acting injectable antipsychotic medications.
- Insight into schizophrenia and attitudes toward treatment were assessed using the Scale to assess Unawareness of Mental Disorder, the Birchwood Insight Scale and the Drug Attitude Inventory, respectively.
- All assessments were made by a rater blinded to group assignment.

# Visits

## *Study Design*

- ❑ **Visit 1 (week # 0) :** Screening for eligibility and initial evaluation.
- ❑ **Visits 2-7 (weeks# 2 to 12) :** Individual therapy sessions (an hour session every two weeks).
- ❑ **Visit 8 (week # 14) :** Post Therapy evaluation.

# Measures

- **Demographics:** Patient race, ethnicity, gender, age, marital status, and education were collected during Visit 1.
- **Compliance to pharmacological treatment**  
Patients were rated as compliant when the injection was confirmed (by the nurse who performed it) and non compliant if the injection was refused or the appointment was missed.
- **Insight** was assessed with:
  - the Scale to Assess Mental Disorders-SUMD which measures several dimensions of "insight" into illness. Independent assessments of patients' current insight into a) having a mental disorder, b) the need for treatment, and c) specific signs and symptoms, will be made. The SUMD is a standardized scale which is rated on the basis of direct patient interview. Only dimensions a and b were assessed in this study as the statistical power was not strong enough to assess the symptomatic dimension. Items score range from 1 to 5. The higher the score the worse the insight.
  - the Birchwood Insight Scale which is a 8 items self-report measure of insight. Total scores range from 0 to 12. The higher the score the better the insight.

# Measures

- **Motivation for Change** was assessed with a semi-structured interview designed for the purpose of this study. First evaluation of motivation for taking the medication took place when patients were about to be discharged. Two forms of this semi-structured interview were developed one for inpatients (Form A- 14 items) one for outpatients (Form B -15 items).
- Five stages of change are related to compliance to pharmacological treatment:
  - **Stage I PRECONTEMPLATION** (patient does not feel the need to take medication),
  - **Stage II CONTEMPLATION** (patient thinks about taking it but does not do it yet),
  - **Stage III PREPARATION** (patient is partially compliant or made some attempts to be),
  - **Stage IV ACTION** (patient has been compliant for less than 6 months),
  - **Stage V MAINTENANCE** (patient has been compliant for more than 6 months).



# Measures

- ***Attitude toward treatment*** was assessed with the Drug Attitude Inventory which is a self-report inventory that refocuses on the subjective effects of neuroleptic medications in-patients with schizophrenia. The scale has 10 items, six of them will be scored as true and four will be scored as false. A correct answer to these items will be scored as plus one.

# Analytic Plan

- Participants were randomly assigned to the LEAP group or to the Rogers group following being discharged from the inpatient unit.
- To determine significant differences between mean scores groups at baseline (compliance, insight, motivation for change and attitudes toward treatment), Mann-Whitney and  $\chi^2$  tests were used.
- To test the main study's hypotheses, we conducted ANCOVA analysis. The primary criteria of this study was to assess the efficacy of LEAP: a psychotherapy based on motivational enhancement and cognitive therapies designed to improve patient's adherence to treatment and motivation to change.

# Descriptive statistics- screened patients at Baseline, N=98.

Clinical rating scale N= 98	Mean score (average, SD)
PANSS total score	89.02 (10.82)
Positive subscale	30.38 (8.93)
Negative subscale	28.22 (6.84)
Global Psychopathology	30.41 (6.53)
Item G12 (insight item)	4.77 (1.59)
Birchwood Insight scale	6.27 (3.32)
Drug Attitude Inventory	-0.04 (4.99)
SUMD item (G1) insight into mental disorders	3.29 (0.99)
SUMD item (G2) insight into the achieved effects of medication	3.23 (2.85)
SUMD item (G3) insight into social consequences	3.53 (2.55)

# Results-Participants

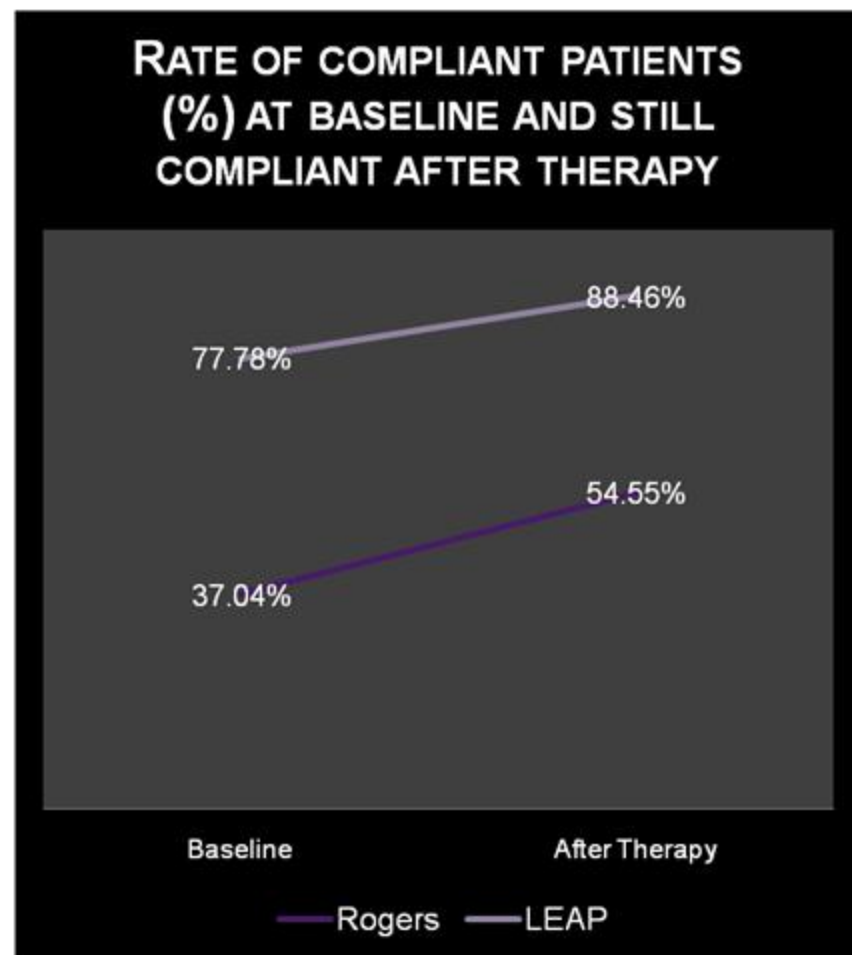
Screened N=98	LEAP Group	Rogers Group
Baseline	N= 27	N=27
Mean age	38.9 (13.1)	40.4 (10.2)
Education	11.6 (2.7)	11.3 (2.7)
Number of Hospitalizations (years)	4.2 (2.2)	4.2 (2.9)
Gender (% male)	48.1 (n=13)	59.3 (n=16)
After Therapy ( + 3 months)	N=26	N= 22

## LEAP maintained compliance to injectable medication (visit 8-week 14)

- Participants were more likely to stay compliant if treated by LEAP compared to patients treated by Rogers therapy.

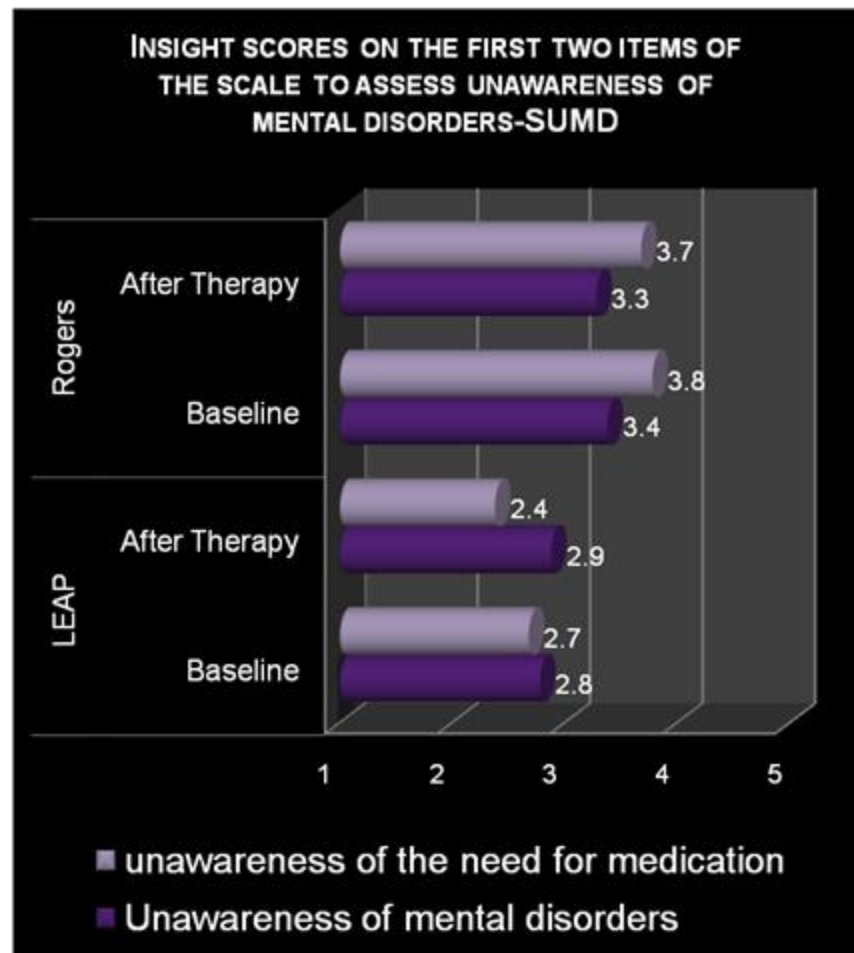
Compliant patients	LEAP	Rogers
N at baseline	27	27
Compliant patients	21	10
N at week 14	26	22
Compliant patients	23	12

$\chi^2$  test ( $\chi^2=4.38$ ;  $df= 1$ ,  $p=.036$ ).



## LEAP improved insight into mental disorders and into the achieved effects of medication (visit 8-week 14)

- Participants had a better insight into mental disorders and into the need for medication if treated by LEAP compared to patients treated by Rogers therapy.
- ANCOVA analysis ( $F(1,40)=2.564, p=.027, n^2=.117$ ) and ( $F(1,40)=12.835, p=.001, n^2=.243$ ) respectively.
- The higher the score the worst the insight.



## LEAP improved attitudes toward treatment (visit 8-week 14)

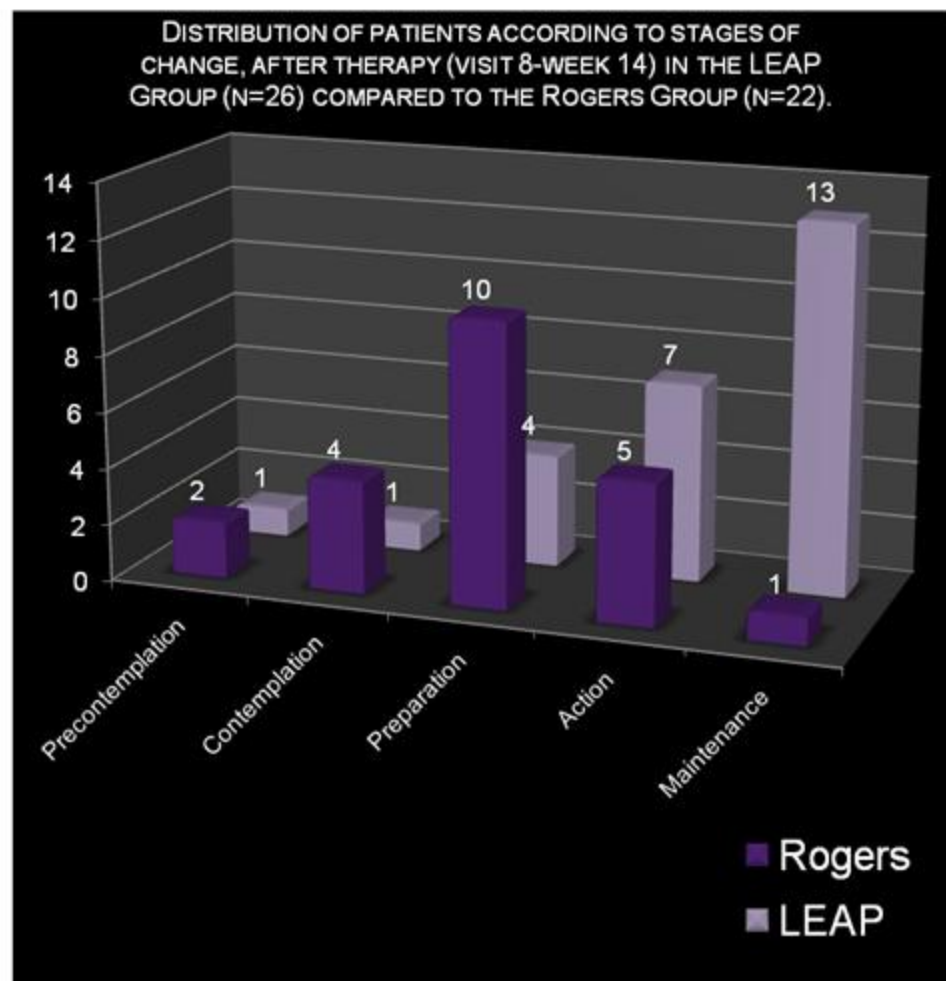
- Participants were more likely to have a better opinion of their medication if treated by LEAP compared to patients treated by Rogers therapy.
- **ANCOVA analysis**  
( $F(1, 40)=5.415, p=.025, \eta^2=.119$ ).

DAI-10 Mean total scores	LEAP	Rogers
Baseline	0.9 (4.7)	0.2 (4.6)
After therapy (week 14)	2.6 (4.6)	-0.2 (4.7)

Total score range from -10 to +10

## LEAP improved motivation for compliance (visit 8-week 14)

- Participants were more likely to be motivated to take their medication if treated by LEAP compared to patients treated by Rogers therapy.
- ANCOVA analysis ( $F(1.40)=9.656, p=.003, n^2=.194$ ).
- Patients are compliant at stages 4 (action) and 5 (maintenance).





# Conclusions

- Results show that compared to the control psychotherapy :
- LEAP maintained compliance to injectable antipsychotics.
  - LEAP improved motivation to take medication.
  - LEAP improved insight into mental disorders.
  - LEAP improved insight into the achieved effects of medication.
  - LEAP improved attitudes toward treatment.

# Strengths and limitations

- Strengths of the experimental design include the randomized blinded group assignment, blinded assessments of the dependent variables and near 100% reliability and validity of the adherence measure.
- Among the limitations of the present study was the absence of a LEAP fidelity measure and the fact that the senior author was the only therapist for all patients and as such could have biased the results by differentially treating patients depending on which therapy they were assigned to.
- This study will be replicated in a larger more heterogeneous sample with a longitudinal assessment of fidelity to the LEAP intervention and a therapist(s) blinded to study hypotheses.

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