

# The Metabolism of a Psychosocial Treatment Intervention in Schizophrenia: The Helpful Habit Program

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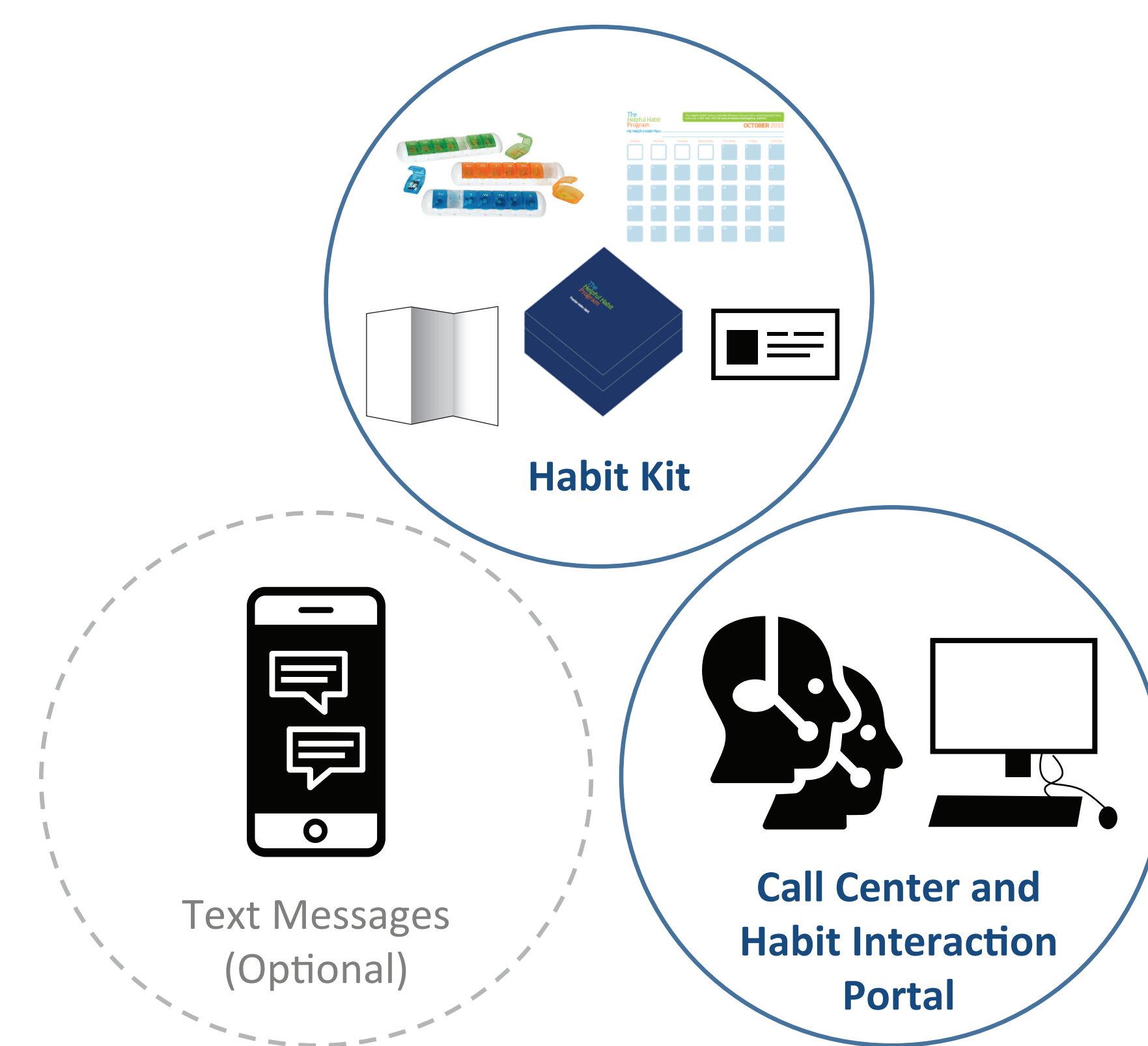
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## INTRODUCTION

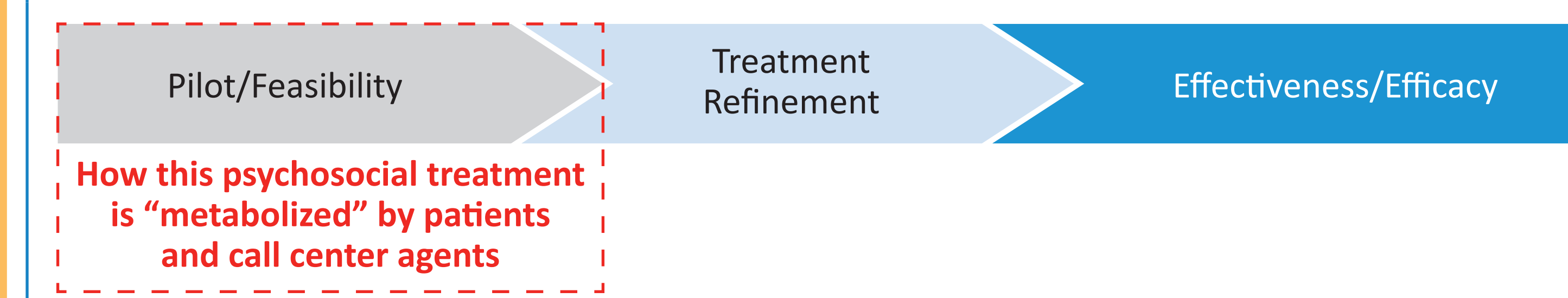
- Poor adherence to medication is highly prevalent in patients with serious mental illness.<sup>1-3</sup>
- A number of psychosocial adherence programs exist to address this problem, yet many are time consuming, require in-person assistance, and are thus resource intensive.<sup>4-7</sup>
- Medication adherence is a repetitive behavior. However, if medication adherence is not automatic, higher-order cognitive capacities need to be invoked in order to ensure the activity.
  - This presents a challenge for patients who are cognitively impaired. In some cases, this burden may be an insurmountable barrier to maintaining adherence.
- The cognitive burden of medication adherence can be greatly reduced or eliminated by making the activity of taking medication a habit.
- With the overarching aim of improving medication adherence in patients, a unique psychosocial intervention (the Helpful Habit [HH] program, **Figure 1**) was designed to personalize and optimize the habit formation process to address nonintentional medication nonadherence in patients with schizophrenia and schizoaffective disorder.
- The program was based on the basic science understanding of habit formation, including learning theory and habit theory as well as behavioral economics and neurobiology.

**Figure 1. Components of the Helpful Habit Program**



- In large-scale (efficacy or effectiveness) intervention studies, attention is not given to how programs are “metabolized” by patients. That is, patients’ perception and takeaways from the intervention vs the intent of the intervention and the extant constraints that affect the patients’ absorption of the intervention.
  - It is important to obtain this information during early evaluation of a psychosocial program; if the program is refined accordingly, such an approach may maximize the potential to impact clinical outcomes.
- The steps in the development of the HH program are shown in **Figure 2**.
- This poster describes the innovative study methodology employed in the first step of the development program to elucidate how this psychosocial treatment was “metabolized” by patients and call center agents.

**Figure 2. Steps in Overall Development of the Helpful Habit Program**



## OBJECTIVES

### Primary Objectives

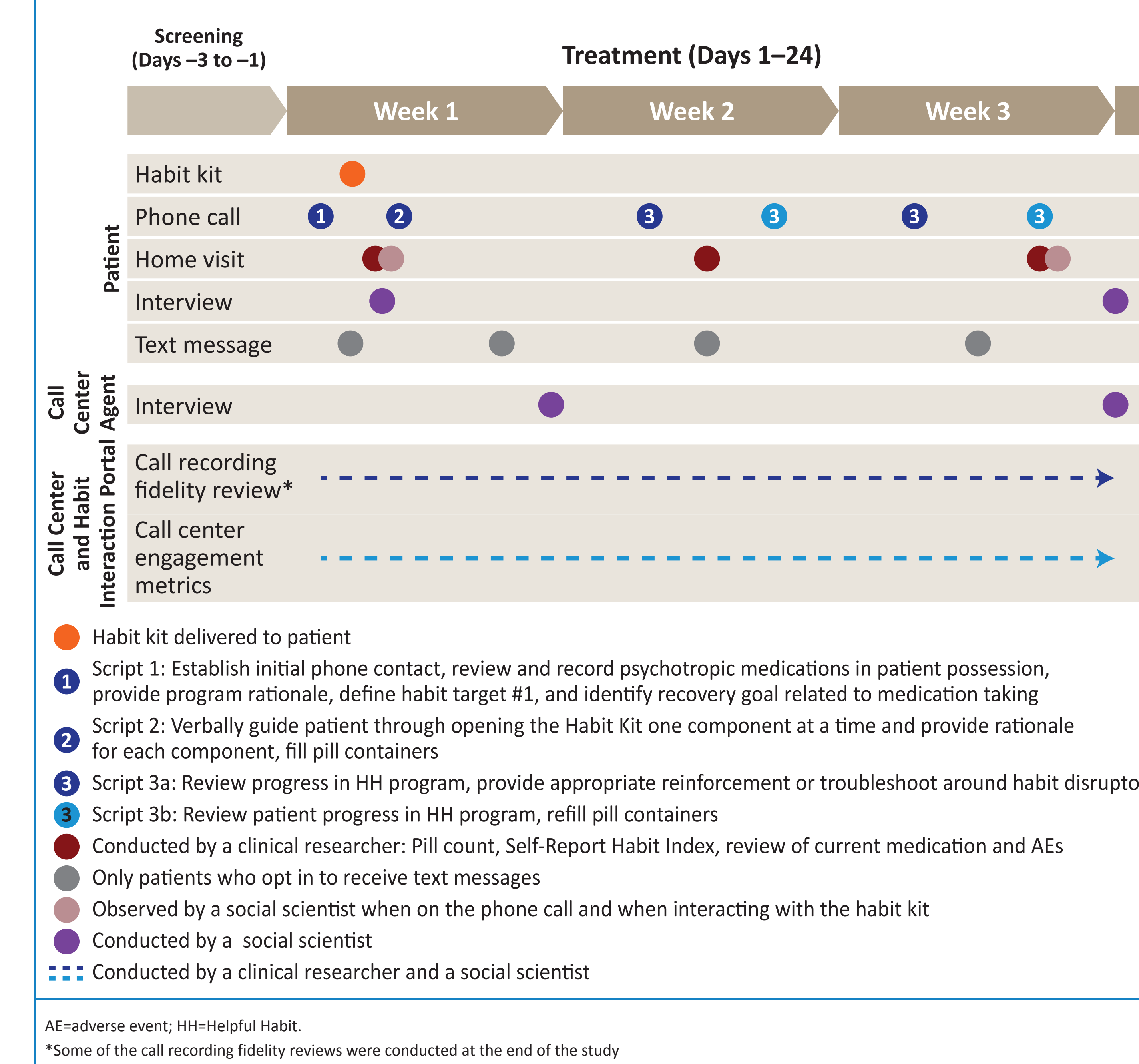
- Gain insight into the ease and feasibility of implementation of the HH program
- Determine modifications for improvement of the program to aid medication adherence habit formation (treatment refinement phase)

## METHODS

### Study Design

- This was a 3-week, interventional, exploratory, refinement study to optimize the HH program (**Figure 3**).
- The study included a screening period (days -3 to -1) and a treatment refinement period (days 1-24).
- Each patient received a habit kit comprising 1 or more pill containers, a welcome booklet, a contact card, and a calendar. A recognition certificate and tokens were provided based on progression through the program.
- Call center agents implemented the HH program on the basis of call scripts.
- All contact with patients was conducted by clinical researchers visiting the patient’s home. Home visits were coordinated with social scientists.
- Social scientists observed interactions during the home visit, interviewed call center agents, and reviewed call recordings.
- The key interactions during the study are shown in **Figure 4**.

**Figure 3. Study Design**



- This study was approved by the local institutional review board and conducted in compliance with the protocol and all other applicable local laws and regulatory requirements.

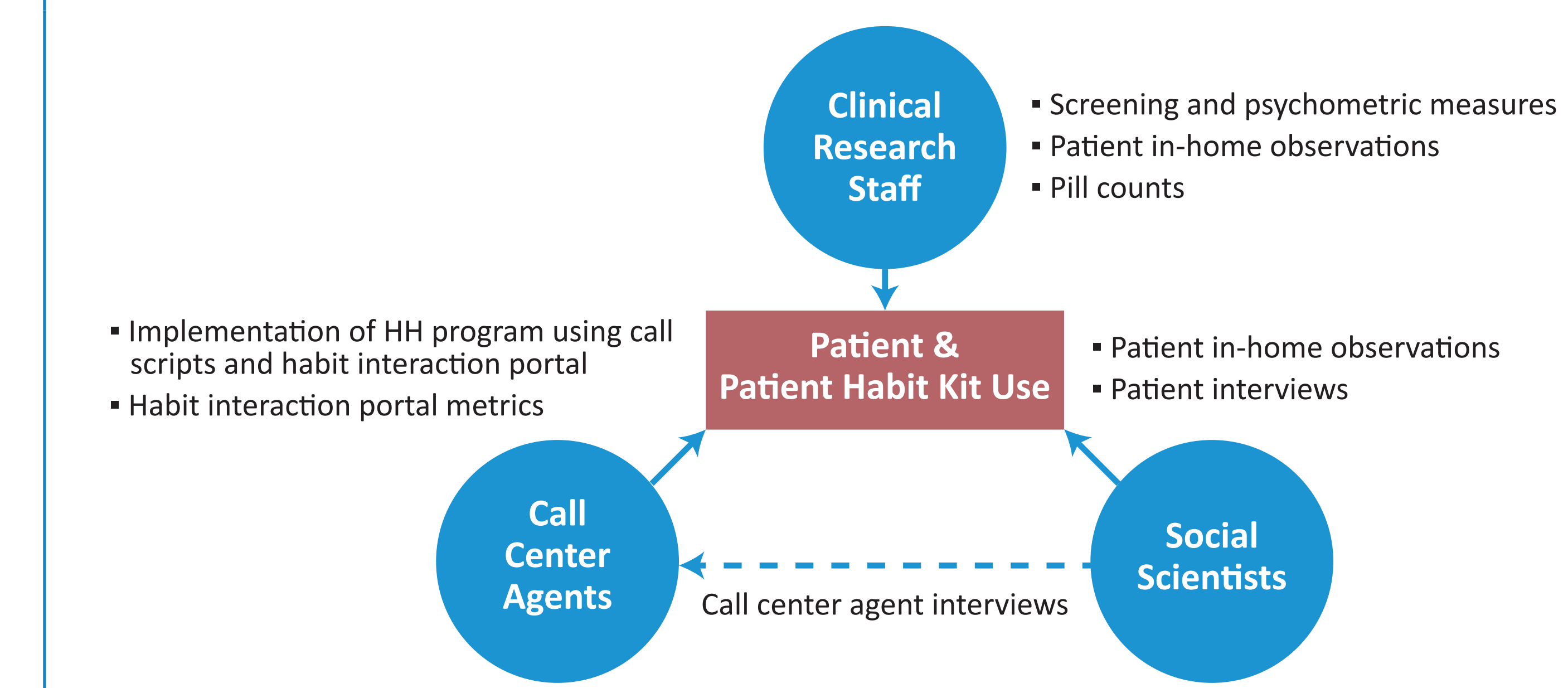
### Patients

- This study included male and female patients 18-65 years of age with a current diagnosis of schizophrenia or schizoaffective disorder as confirmed by the principal investigator who were currently prescribed medication to treat their schizophrenia or schizoaffective disorder.
- All patients signed an informed consent form before participation in the program.

### Assessments at Screening

- Brief Interview for Reasons for Missed Doses
- Morisky Medication Adherence Scale (MMAS-8 item)
- Clinical Global Impression-Severity Scale
- iPad version of the Brief Assessment of Cognition
- Specific Levels of Functioning Scale
- Columbia-Suicide Severity Rating Scale-Baseline/Screening

**Figure 4. Key Interactions in the Study**



### Endpoints

#### Primary Endpoint

- The primary endpoint was the degree to which the HH program was implemented appropriately over the study period and the association of fidelity and quality with outcomes.
- The primary endpoint measures were:
  - Patient pill count and patient self-report adherence behavior (MMAS-8 item)
  - Patient self-report about the degree of medication-taking automaticity (Self-Report Habit Index)
  - Fidelity assessed by 2 independent reviews of the call recordings. Social scientists evaluated the call recordings to locate potential shortcomings with the script and habit interaction portal. Scripts were coded when call center agents adjusted the script intentionally and exhibited some form of speech hesitation, signaling a problem in the script or usability problem in the portal. Clinical researchers listened to the call recordings to evaluate quality of delivery.

#### Secondary Endpoints

##### Habit Kit

- Observation of patients’ ability to set up and use the Habit kit over the study period (ie, environmental context for kit use, interactions with the kit, placement of the kit)

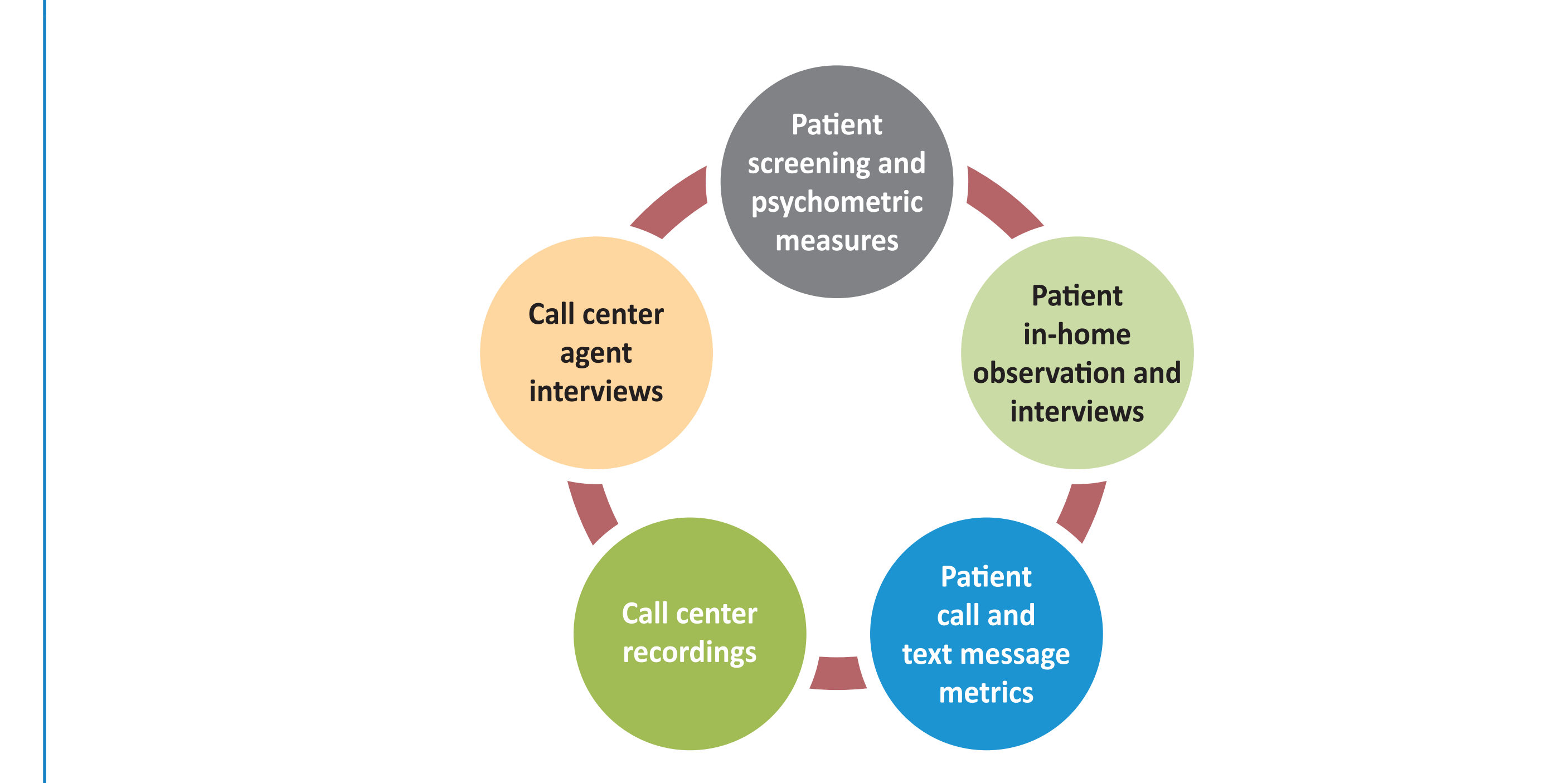
##### Call Scripts and Software Interface

- Effectiveness of call scripts and software interface to get information needed to progress during each call and throughout the study period
- Feasibility metrics for call center agents’ interactions during calls

##### Treatment Alliance

- Patient overall experience and perception about call center agents’ level of interest in helping the patient; degree of alignment between patient behavior and verbal feedback
- Call center team’s overall experience, perception about alignment with patients, and impact of call script and software interface on the ability to help the patient

**Figure 5. Study Data Sources**



### Call Center Agents’ Performance and Satisfaction

- Ease of using and adhering to HH program call scripts and software interface
- Understanding of the purpose of the HH program
- Satisfaction with scripts, software, and the overall program

### Patient Performance and Satisfaction

- Helpfulness of and satisfaction with the Habit kit, interactions with the call center agents, and overall program for achieving relevant patient goals
- Understanding of the HH program
- Habit disruptors and facilitators for achieving medication-taking and recovery goals

### Text Messaging

- Feasibility metrics for text messaging service (for patients who chose to opt in)

### Safety

- Clinical research staff captured adverse events (AEs).
- All AEs were coded by system organ class and Medical Dictionary for Regulatory Activities (version 18) preferred terms.

### Data Analyses

- Figure 5** shows sources of data analyzed in the study.
- Qualitative and quantitative analyses of data from enrolled patients were conducted.
  - Descriptive statistics were used for analyses of data from quantitative assessments.

## SUMMARY

- The methods employed in this study represent a unique approach to the conduct of the pilot phase during development of a psychosocial treatment program.
- These innovative and diverse methods of data collection facilitate program refinement and may offer new insights into the way in which psychosocial treatments are “metabolized” by patients with schizophrenia.

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## ACKNOWLEDGMENTS

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## DISCLOSURES

John Docherty and Ainslie Hatch are employees of ODH, Inc. Deborah Profit and Erica Lawson are employees of Otsuka Pharmaceutical Development & Commercialization, Inc. Anke Adenwala is an employee of GfK Custom Research, LLC, contracted by ODH, Inc. Dawn Velligan is a paid consultant for ODH, Inc.