

The background of the slide is a stylized house shape. The roof is a white triangle pointing upwards, outlined in blue. The walls are two large triangles meeting at a point at the bottom center. The left wall is a solid blue triangle, and the right wall is a solid orange triangle. The text is centered within the white roof area.

Investigational Products

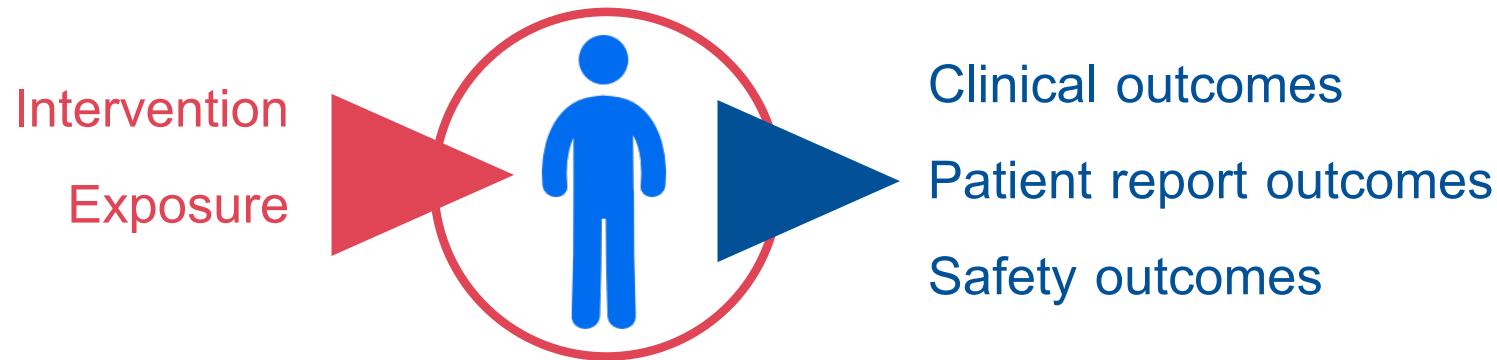
Social & Behavioral Intervention

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**Behavioral & Psychological
Intervention
Social intervention/program**

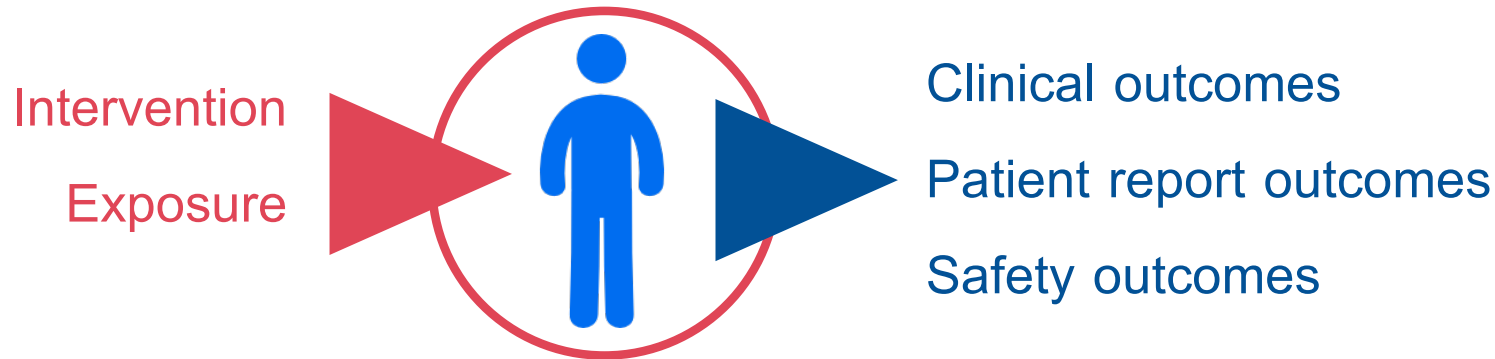
11 February 2019

Compliance with Intervention



- Non-compliance affect
 - 1) Accuracy and reliability of outcomes/responses
 - 2) Subjects' safety (may place subjects at risks)

Compliance with Intervention



- Causes of non-compliance

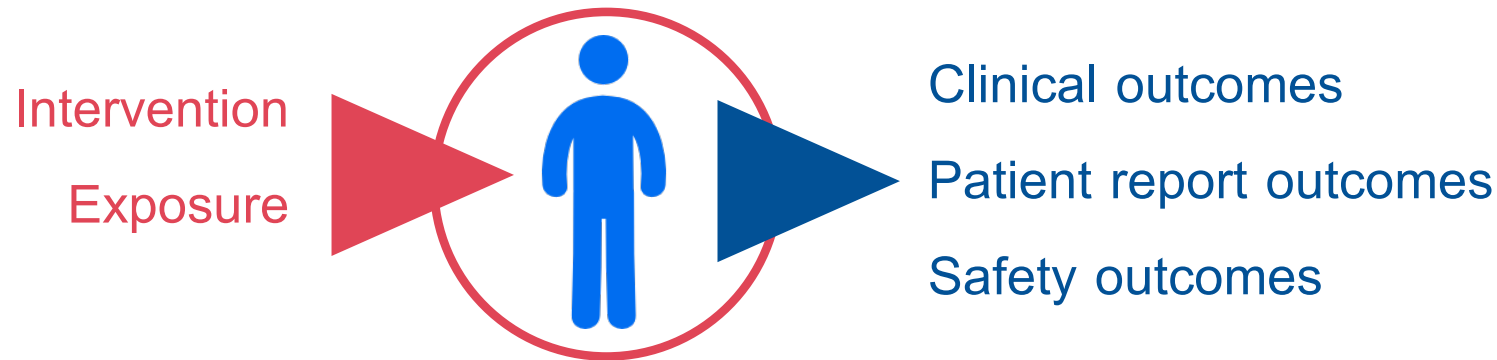
- 1) Investigator and team
- 2) Subjects
- 3) Sponsor

- Not aware
- No skill

- Not aware
- Not friendly use or uncomfortable
- Ineffective or safety concern

- No monitoring or tracking
- No training or standardizing the process

Compliance with Intervention



- Causes of non-compliance
 - Protocol

- Inadequate details
- Not clear
- Inconsistent

Compliance with Intervention

- Protocol provide details of รายละเอียดในโครงการวิจัย
 - a) Rationale & evidence support the intervention model
หลักการ เหตุผล และการศึกษาที่ผ่านมาของ intervention
 - b) Content and exposure/dose of intervention
รายละเอียด ขั้นตอน/วิธีการ และขนาดการให้ของ intervention
 - c) Exposure time or contact of intervention
 - d) Time or frequency of administration
ระยะเวลาการให้หรือเข้าร่วมของ intervention และความถี่
 - e) Exposure/dose titration, if required
การปรับขนาด
 - f) Concomitant treatment/intervention
การรักษาพร้อม

Enhance Intervention Fidelity


- A. Knowledge and skills ความรู้และทักษะ
 - a) Instruction/treatment manual or scripted intervention protocol คู่มือ หรือคำแนะนำ
 - b) Training and standardization of training การฝึกอบรม และมาตรฐานการฝึกอบรม
 - c) Developing and maintaining skills การพัฒนาทักษะและการคงทักษะไว้

Enhance Intervention Fidelity

- B. Intervention monitoring to ensure that administration of intervention is การติดตามและกำกับดูแลทักษะ
 - a) accurate and consistent and
 - b) in accordance with the approved protocol
- C. Monitoring tools
 - a) Checklist or administration log
 - b) Subject Self-Report Questionnaire or Diary
 - c) Qualitative interviews
 - d) Audio-taped sessions
 - e) Direct observation

Enhance Intervention Fidelity

- D. Assessment of intervention received
 - a) Physiological assessment
 - b) Subjects' perception or knowledge
 - c) Subject's' confidence

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- the Resources for Enhancing Alzheimer's Caregiver Health (REACH II) program (Clin Trials, 2006; 3(2): 107-118)
 - Caregiver death, hospitalization, emergency room visit,
 - Care recipient death, hospitalization, emergency room visit, severe medical problem