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Supplementary Material

Article Title: Phase 3b Multicenter, Prospective, Open-Label Trial to Evaluate the Effects of a Digital Medicine System on Inpatient Psychiatric Hospitalization Rates for Adults With Schizophrenia

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List of Supplementary Material for the article

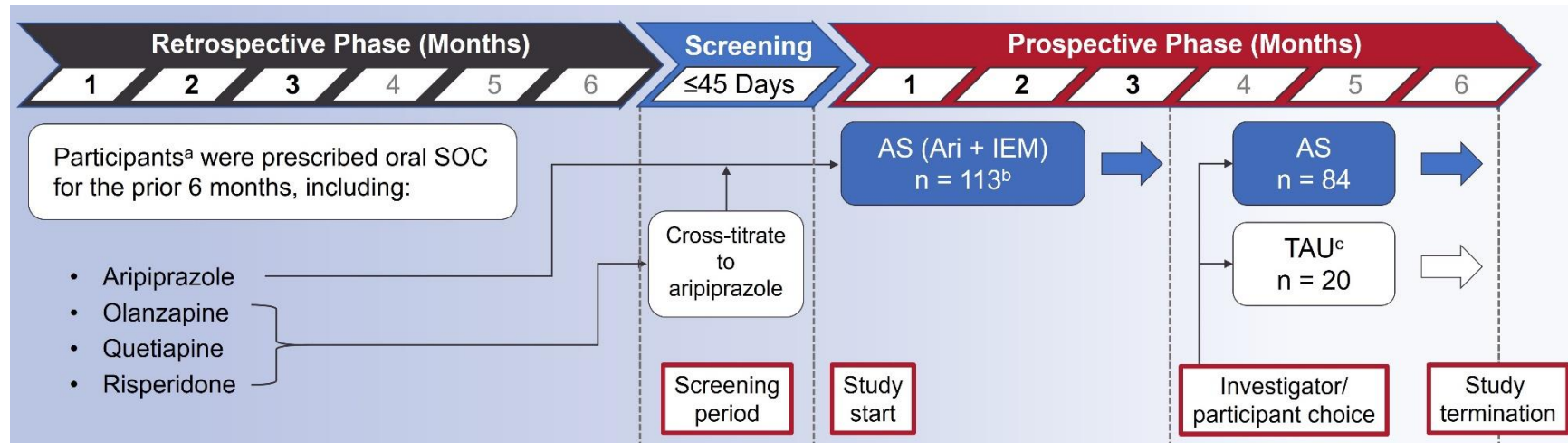
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SUPPLEMENTARY MATERIAL

Supplementary Figure 1. Study Design



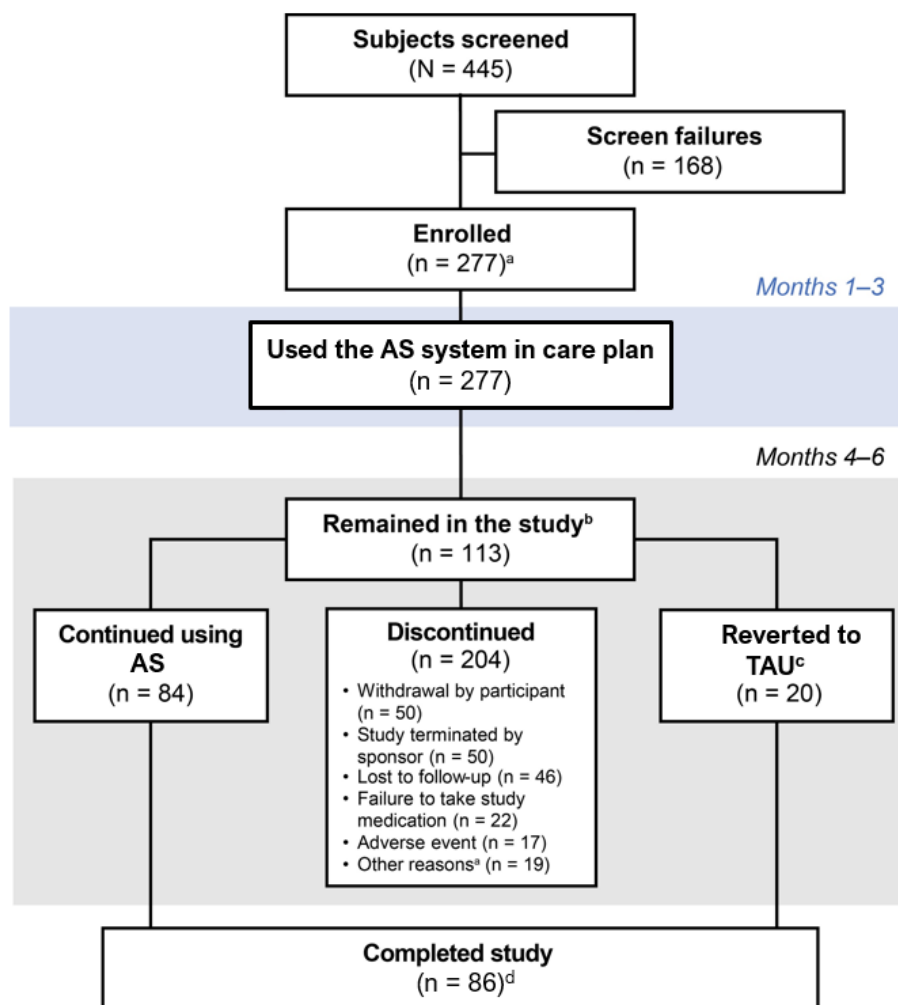
^aPrimary inclusion criteria: men and women aged 18–65 years, diagnosis of schizophrenia per DSM-5, ≥ 1 inpatient psychiatric hospitalization in the preceding 4 years, prescribed oral antipsychotics for ≥ 6 months, owned and were able to use a smartphone, skin at lower edge of rib cage devoid of dermatologic problems. Excluded were participants treated with an LAI antipsychotic, diagnosed with a mental disorder other than schizophrenia, comorbid psychiatric conditions, or with an allergy to adhesive tape or any other components of the AS system.

^bThe mITT population included participants who either completed 3 months with AS or who took ≥ 80% of the study medication for the indicated portion of the prospective phase (eg, months 1–3 or months 1–6). Nine participants discontinued on or before month 3 but were included because they had ≥ 80% adherence to the AS system. The ITT population (N = 277) included participants who received ≥ 1 dose of the study medication.

^cTAU included 19 participants who opted for oral SOC and 1 participant who chose LAI antipsychotic therapy.

Abbreviations: Ari = aripiprazole, AS = aripiprazole tablets with sensor, DSM-5 = Diagnostic and Statistical Manual of Mental Disorders, 5th edition, IEM = ingestible event-marker sensor, LAI = long-acting injectable, (m)ITT = (modified) intent-to-treat, SOC = standard of care, TAU = treatment as usual.

Supplementary Figure 2. Participant Disposition



^aOther reasons for discontinuation included physician decision (n = 8), protocol deviation (n = 3), lack of efficacy (n = 1), pregnancy (n = 1), withdrawal by caregiver (n = 1), and other (n = 5).

^bA total of 113 participants remained in the study past month 3; of these, 20 switched to TAU, including 19 participants who opted for oral SOC and 1 participant who chose LAI antipsychotic therapy. Eighty-six participants met criteria for the mITT population in months 1–6, 17 of whom took oral SOC. Twenty-seven participants withdrew before 6 months and did not meet criteria for the mITT population in months 1–6, 3 of whom took oral SOC before discontinuation of the study.

^cTAU included 19 participants who opted for oral SOC and one participant who chose LAI antipsychotic therapy.

^dSeventy-three participants completed 6 months' use of the AS system, whereas 13 participants took $\geq 80\%$ of their study medication.

Abbreviations: AS = aripiprazole tablets with sensor, LAI = long-acting injectable, SOC = standard of care, TAU = treatment as usual