Assessing **C**ommunication and **C**linical **E**ffectiveness of **S**elf-managed **S**peech-language Therapy: a randomized control trial of a novel digital therapeutic in individuals with post-stroke aphasia (**ACCESS**)

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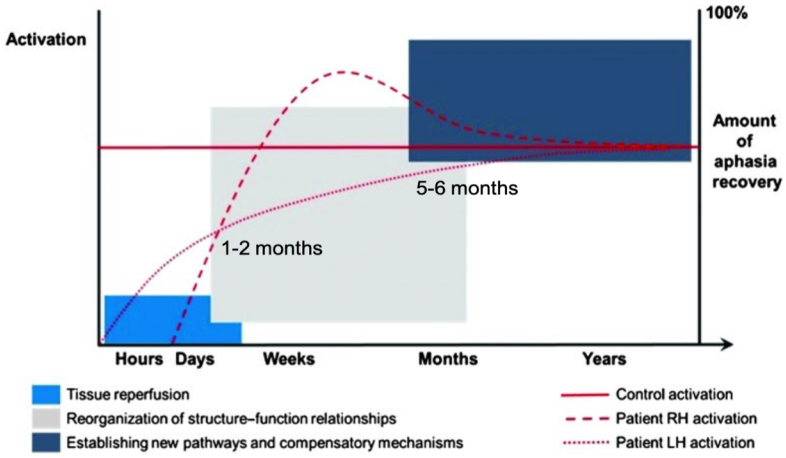
Aphasia is…

- **common**
  - ~1/3 of all stroke survivors | affecting 2M individuals in U.S. alone[1]
- **debilitating**
  - Linked to higher overall mortality, reduced functional recovery, reduced rates of return to work, social isolation & reduced QoL[2-5]
- ***treatable***
  - Behavioral speech-language therapy (SLT) results in clinically significant improvements in language and communication outcomes[6]

[1]National Aphasia Association (NAA) Aphasia Fact Sheet ; [2]Laska et al., J Int Med (2001); [3]Paolucci et al., Cerebrovascular Diseases (1998); [4]Bhogal et al., Stroke (2003); [5]Bakheit et al., Clin. Rehab. (2007); [6]Brady et al., Cochrane Database Syst Rev. (2016)

SLT: State of the evidence

- Timing
  - Good evidence for SLT-induced improvement in *chronic* phase[1-3]
  - Equivocal evidence for improvement in *very early acute* phase[4-7]
  - Limited evidence for *subacute* phase[8-11]
    - Potential for disease trajectory modifying tx



Kiran, Meier & Johnson, 2019

[1]Brady et al., Cochrane Database Syst Rev. (2016); [2]Breitenstein et al., The Lancet (2017); [3]Palmer et al., Lancet Neurol. (2019); [4]Godecke et al., Int J Stroke (2012); [5]Godecke et al., Int J Stroke (2020); [6]Laska et al., Cerebrovasc Dis Extra (2011); [7]Nouwens et al., European Stroke Journal (2017); [8]Bakheit et al., Clin. Rehab. (2007); [9]Martins et al., Int J Lang Comm Dis (2013); [10]Sickert et al., JNNP (2014); [11]van der Meulen et al., Neurorehab Neural Repair (2014); [12]Bhogal et al., Stroke (2003); [13]Skolarus et al., Stroke (2017); [14]Cavanaugh et al., AJSLP (2021); [15]ASHA National Outcomes Measurement System: Adults in Healthcare–Outpatient National Data Report 2019

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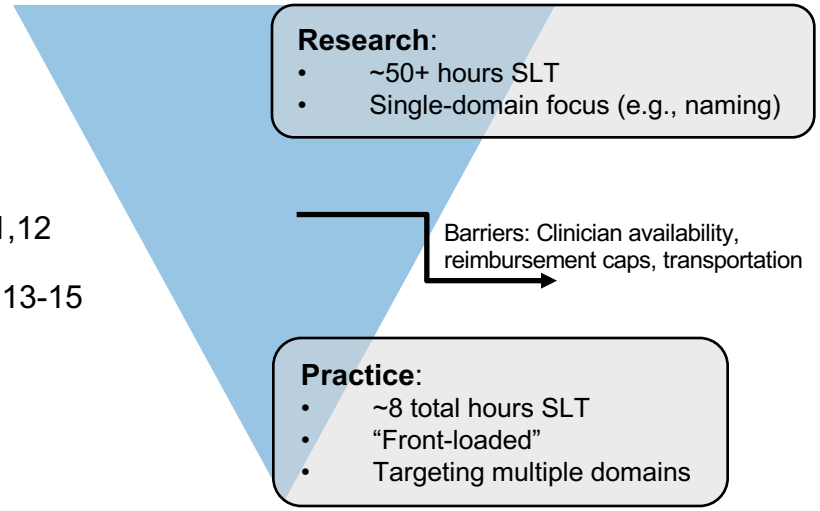
- Intensity
  - High intensity &/or dosage SLT → improved communication outcomes[1,12]
  - Dosage gap b/w research & practice[13-15]



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Digital health advances in SLT

- Digital therapeutics enable effective, high intensity therapy at home
  - Reduce traditional barriers to access[1,2]
  - Well-established for post-stroke motor rehab[3-6]
- Emerging clinical trial evidence for efficacy in aphasia
  - Single-impairment therapies for naming, sentence production, auditory comprehension[7-11]
  - **Few studies of comprehensive, self-managed therapies**[12]

[1]Hall et al., Int J Telerehabil. (2013); [2]Weidner & Lowman, Perspectives of the ASHA Special Interest Groups (2020); [3]Lin et al., Stroke (2018); [4]Chen et al., Int J Med Inform (2019); [5]Cramer et al., JAMA Neurol (2019); [6]Cramer et al., Front Neurol (2020); [7]Palmer et al., Lancet Neurol. (2019); [8]Woolf et al., Clin Rehabil (2016); [9]Kurland et al., JSLHR (2018); [10]Furnas et al., Aphasiology (2014); [11]Fleming et al., JNNP (2020); [12]Braley et al., Front Neurol (2021)

Constant Therapy digital health platform

- Commercially available app with 400K users worldwide, including 37K clinicians

Therapy Ingredients	Mechanisms of Action
Prescribed regimen Evidence-based tasks are assigned to users based on the skills they selected for improvement	Enables **self-managed** practice without clinician supervision
Ease of access Patients do therapy at home & on-demand	Enables & encourages **intensive** therapy practice
Task variety 100,000+ stimuli items spanning 14 different speech, language and cognitive skill domains	**Comprehensive** therapy targets multiple skills simultaneously
Personalized goal setting Upon registration, patient selects skills to practice	**Personalized** goals increase motivation & buy-in

Clinical evidence for Constant Therapy

Preliminary clinical evidence

Study	*Subjects*	*Main Finding*	*RCT?*
Des Roches et al., 2015[1]	Persons with aphasia (PWA) (N=51)	At-home CT + in-clinic practice → greater improvement in language compared to in-clinic practice only	×
Godlove et al., 2019[2]	PWA, acute + chronic (N=3,686, *retrospective analysis*)	At-home CT → more frequent practice & faster task mastery compared to in-clinic CT	×
Braley et al., 2021[3]	PWA, chronic (N=32)	Intensive, **10-week regimen** of CT led to greater improvement in **WAB-R AQ** scores compared to **active control** workbook therapy	✓

- CT has promising evidence but **has not yet been studied in full-scale RCT or in acute recovery**

[1]Des Roches et al., Front Human Neuroscience (2015); [2]Godlove et al., Front Neurol (2019); [3]Braley et al., Front Neurol (2021)

Primary aim

1. Determine whether use of Constant Therapy (CT) improves language recovery over 10 week treatment period, vs. self-managed workbook practice (WB) and usual care (UC)
   i. In the **subacute** phase (1-2 months post-stroke), determine whether CT intervention is superior to UC
   ii. In the **chronic** phase (5-6 months post-stroke), determine whether CT intervention is superior to (a) WB, (b) UC

Primary Outcome: Western Aphasia Battery Aphasia Quotient (WAB-R AQ) at 10 weeks

Central Hypothesis: CT intervention is superior to active and usual care comparators, in both subacute and chronic post-stroke stages

Participants

Inclusion

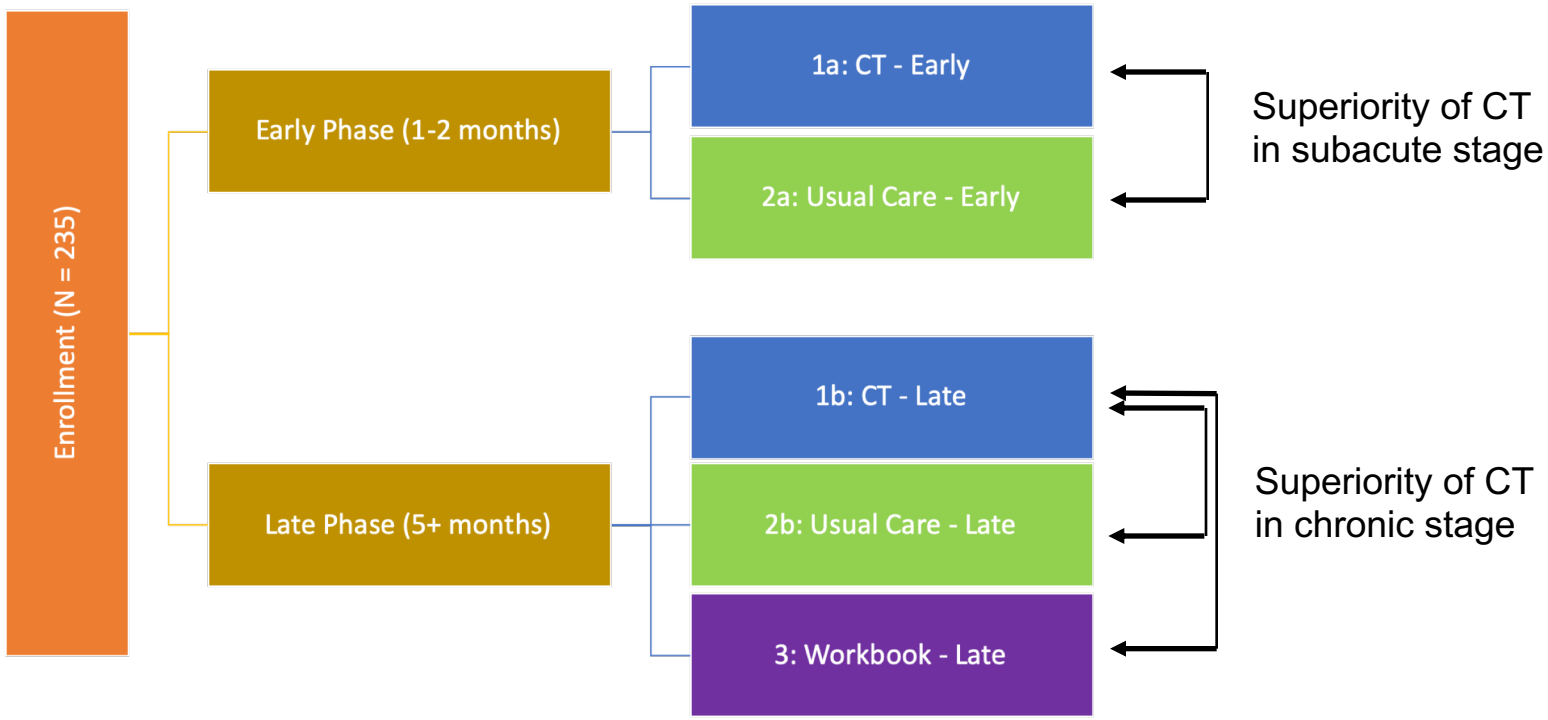
- **Left-hemisphere ischemic or hemorrhagic stroke resulting** in speech, language with or without cognitive deficits
- **Confirmed aphasia** (Quick Aphasia Battery < 8.9)
- **1-2 months post-stroke** at time of enrollment, recruitment of potential participants can begin any time after stroke
- **Medically stable** and discharged from hospital or rehabilitation setting
- **18 – 80 years old** at time of consent
- Premorbid **fluency in English**
- **Family member or care partner** willing and able to help with delivery of therapy over the duration of the study period

Exclusion

- **Major, active neurological condition(s) other than stroke**
- History of **cognitive impairment unrelated to stroke**
- History of **symptomatic stroke prior to index stroke**
- **Severe uncorrected vision and/or hearing** problems likely to impact study participation
- Current diagnosis, determined through patient self-report, of **major clinical depression** (PHQ-9 > 9) or **other psychiatric conditions** likely to impact study participation
- **Pre-stroke diagnosis of learning or language disorder**
- **MoCA memory scores ≤ 7**
- **Severe apraxia of speech or dysarthria**, as determined by a clinician based on performance on the Apraxia of Speech Rating Scale and/or medical records
- Completion of **≥ 50 Constant Therapy items** in last 60 days

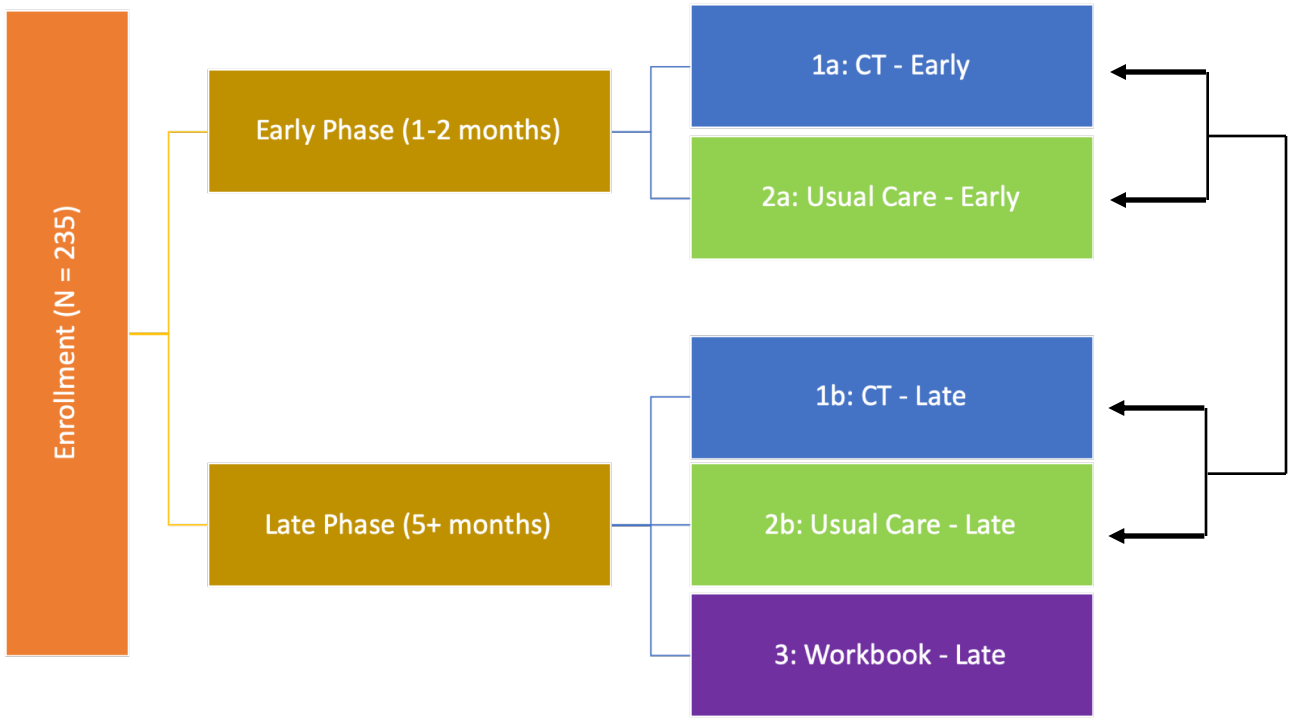
Study design

	Outcome(s)	Comparison
Aim 1 (primary)	WAB-R AQ	• 1a v. 2a • 1b v. 2b v. 3
Aim 2	Other Language, Cognitive, QoL	

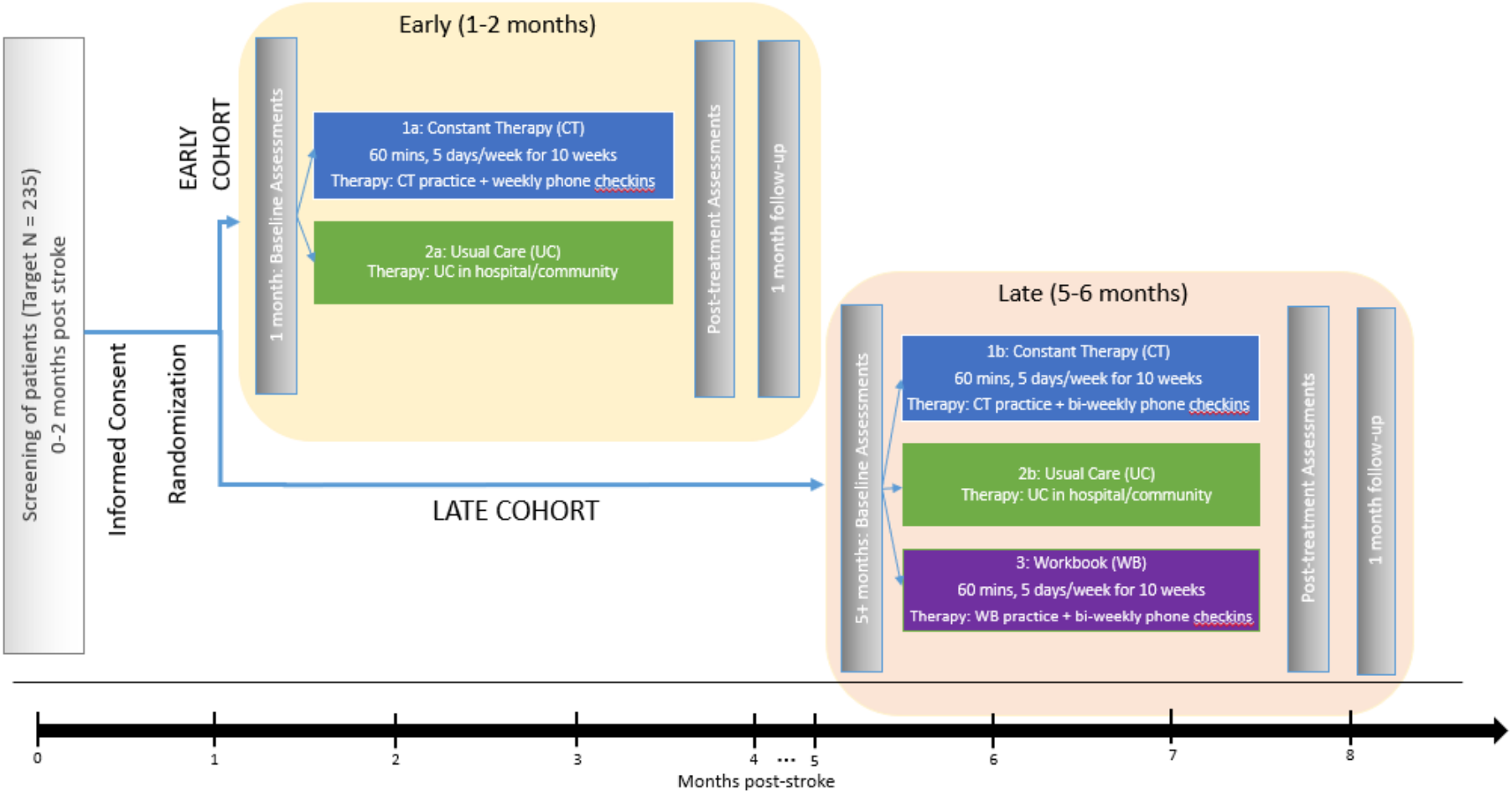


Study design

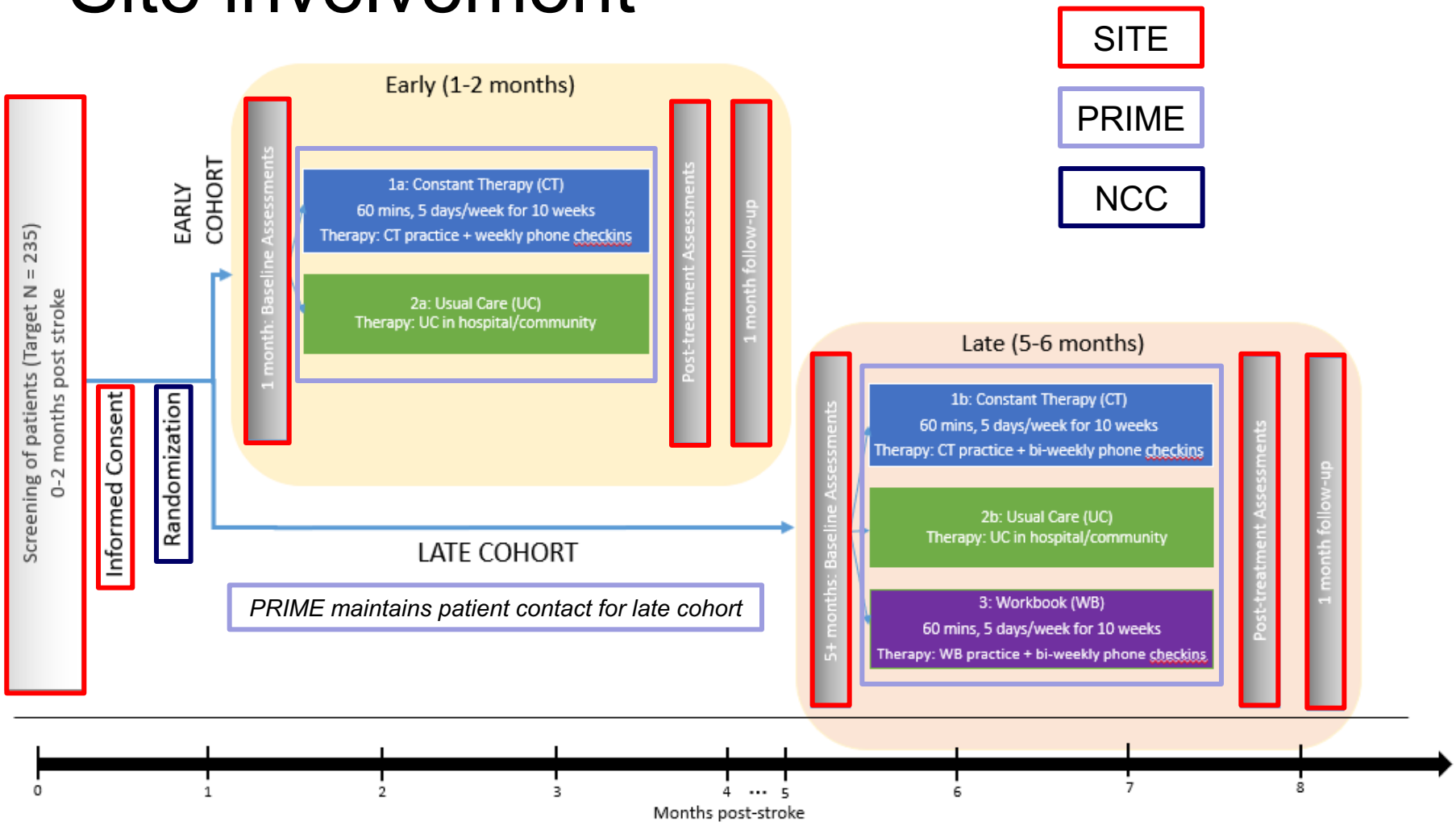
	Outcome(s)	Comparison
Aim 3	WAB-R AQ	• (1a - 2a) v. (1b - 2b)



Study Design and Timing



Site involvement



Successful outcomes from ACCESS

- **Provide critical scientific insight** into timing of SLT
  - Recovery can be modified with acute intensive treatment
- **Transform the clinical landscape** of evidence-based SLT for individuals with post-stroke aphasia
  - ***Improve communication outcomes regardless of aphasia type or severity*** with full suite of personalized, comprehensive therapy
  - ***Enable access to SLT & mitigate inequities of service delivery*** with self-managed, at-home, low-cost therapy
  - ***Equip clinicians with tools to optimize practice***, considering COVID-induced disruptions to traditional service delivery models