

|  |
| --- |
| Link2Care Agenda |
| Quarter 3 [2020] |
| September 16, 2020: 10:00 – 11:00 AM |

# Action Items

|  |
| --- |
| 1. Study Update |
| 1. COVID-19 Update / Recruiting |
| 1. Budget and staffing |
| 1. Ways to improve EMA compliance and phone loss 2. Post-Meeting: Jenn, Michael, Brad and James schedule bi-weekly meetings |

Contents

[Action Items 1](#_Toc42615785)

[Study Participants 3](#_Toc42615786)

[Phone and Clincard Breakdown 5](#_Toc42615787)

[Phone Terminations 6](#_Toc42615788)

[Visit Compliance 7](#_Toc42615789)

[COVID -19 7](#_Toc42615790)

[EMA Completion Rates 8](#_Toc42615791)

[Arrests 10](#_Toc42615792)

[Bridge Case Session Minutes 11](#_Toc42615793)

[Recruitment 12](#_Toc42615794)

Link2Care Study Update

**N =** **n\_participants Participants as of** **date**

# Study Participants

Bm table\_1\_ft bm

|  |  |
| --- | --- |
| **Table 2.** Demographic characteristics of all people screened-out (n=38). | |
| **Age in years**, mean(SD) | 45.7 (10.5) |
| **Gender**, n(%) |  |
| Male | 34 (89.5) |
| Female | 4 (10.5) |
| Other | 0 (0.0) |
|  |  |
| **Race**, n(%) |  |
| Black or African American | 29 (76.3) |
| White | 7 (1849) |
| Other | 2 (5.3) |
|  |  |
| **Ethnicity**, n(%) |  |
| Non-Hispanic | 36 (94.7) |
| Hispanic | 2 (5.3) |

|  |  |
| --- | --- |
| **Table 3.** Distribution of reasons for screen-out. | |
| **Reason For Screen Out:** | N |
| Score <4 on REALM-SF | 26 |
| Incorrect ICF Reading | 2 |
| Score >24 on Mini-Mental State Exam | 4 |
| PT Plans to Move | 1 |
| Failure to Orient | 3 |
| Not Enrolled in Bridge Recovery Program | 0 |
| Other | 2 |
| Total | 38 |

# Phone and ClinCard Breakdown

|  |  |
| --- | --- |
| **Table 4**. Payment card and phone loss. | |
| Total number of ClinCards distributed | 429 |
| Total number of participants with ClinCard replacements | 119 |
| Total number of phones distributed | 240 |
| Total number of participants with phone replacements | 83 |

* 73 Participants had cards replaced 1 time (2 total payment cards).
* 29 Participants had cards replaced 2 times (3 total payment cards).
* 13 Participants had cards replaced 3 times (4 total payment cards).
* 4 Participants had cards replaced 4 times (5 total payment cards).

|  |  |
| --- | --- |
| **Table 5.** Phone distribution and replacement. | |
|  | N (%) |
| Total # of phones distributed overall | N=240 |
| Total # of participants in phone groups | 151 |
| Total # of participants w/ phone replacements | 83 |
| # of participants w/ phone replacement (**UCM+SP**) | 35 |
| # of participants w/ phone replacement (**L2C**) | 48 |
| # of participants in UCM+SP w/ >1 phone replacement | 3 |
| # of Participants in L2C w/ >1 phone replacement | 3 |

* 77 Participants had phone replaced 1 time (2 phones per participant total).
* 3 UCM+SP participants (2010, 2165, 2168) & 3 L2C participants (2099, 2124, 2189) replaced phone 2 times (3 phones per participant total) due to phone malfunctions.

# Phone Terminations

|  |  |  |  |
| --- | --- | --- | --- |
| **Table 6.** Reasons for phone terminations by informed consent form iteration | | | |
|  | **ICF #1**: Original EMA Structure  (P2001-P2073) | **ICF #2:** 15-Day EMA Comp & Non-compliance  (P2074-2153) | **ICF #3:** Increased EMA Payment  (P2154 and on) |
| **Reasons for Terminations** | **Number** | **Number** | **Number** |
| Lost | 14 | 15 | 4 |
| Stolen | 34 | 23 | 27 |
| Non-Compliance | 0 | 20 | 9 |
| Sold or Gifted | 2 | 3 | 7 |
| Broken | 2 | 6 | 2 |
| Defective | 1 | 3 | 6 |
| Completed Study | 24 | 12 | 14 |
| Returned to Staff | 0 | 1 | 2 |
| **Total** | **77** | **83** | **71** |

# Visit Compliance

|  |  |  |
| --- | --- | --- |
| **Table 7**. Grouping and compliance for in person visits (n=243). | | |
| **Treatment Condition** | **N** |  |
| UCM | 75 |  |
| UCM+SP | 76 |  |
| L2C | 74 |  |
| Pending V2 | 1 |  |
| No Show V2 | 15 |  |
| Dropped | 3 |  |
|  |  |  |
| **Visit Compliance, %** |  | **Excluding No Show V2 PTs (N=227)** |
| 1 | 243 (100%) | ---- |
| 2 | 227 (93.8%) | 100% |
| 3 | 169 (71.0%) | 75.0% |
| 4 | 131 (56.0%) | 59.0% |
| 5 | 122 (54.2%) | 57.0% |
| Note: There were 15 participants that did not attend V2. | | |

# COVID -19

|  |  |
| --- | --- |
| **Table 8**. COVID-19 Phone Interviews (N=56) Since Protocol Change on 3/17/2020. | |
|  | Number of Participants |
| **Overall** | **56** |
| *L2C Groups* |  |
| UCM | 20 |
| UCM+SP | 19 |
| L2C | 17 |
| *L2C Visits* |  |
| Visit 2 | 1 |
| Visit 3 | 16 |
| Visit 4 | 22 |
| Visit 5 | 17 |
| Notes. N=total number of phone interviews conducted. Some participants have had >1 remote interview. | |

# EMA and Study Completion Rates

|  |  |  |
| --- | --- | --- |
| **Table 9**. EMA completion over 15-day cycle (12 cycles total) | | |
|  | Median EMAs Completed (Range) | Number of PTs who completed 7+ EMAs per cycle (% of PTs) |
| Initial payment approach1 | 1.5 (1.2-5.3) | 10 of 47 (21.3%) |
| Revised payment approach (payment every 2 weeks)2 | 3.8 (0.7-9.9) | 37 of 96 (38.5%)3 |
| 1Initial payment approach includes PTs 2001-2073 and included payments at study visits only.  2 Revised payment approach includes PTs 2074-2225. The protocol change became effective on 11/21/2018.  3Only includes PTs who completed the study on or before August 31, 2020. | | |

* Doubled compensation for EMA completion.
  + 1st participant 2153 initiated 6/24/19.
* First app blocker installed.
  + 1st Participant 2165 on 7/25/19.
  + 69 app blockers installed to date

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Table 10A**: Median number of EMAs completed per cycle by number of visits attended between V3 and V5\* | | | | |
|  | EMAs completed by visits attended between V3 & V5, median (Range) | | | |
| 0 Visits | 1 Visit | 2 Visits | 3 Visits |
| ***Pre-Covid-19 protocol (through March 2020, n=111)*** | | | | |
| **Overall** | **0 (0-5.3)** | **0 (0-5)** | **3.2 (1.7-4.4)** | **5.3 (1.5-9.1)** |
| UCM+SP (N=56) | 0 (0-1.4) | 1.3 (0-5.8) | 2 (1.6-3.7) | 5.3 (1.5-9.3) |
| L2C (N=55) | 0.3 (0-9) | 0 (0-5) | 0.5 (1.7-6) | 3.3 (1.5-7.8) |
| ***Post-Covid-19 protocol (through August 2020, n=143)*** | | | | |
| **Overall** | **0.3 (0-0.6)** | **1.4 (0.6-2.2)** | **2.9 (1.4-8.7)** | **8.2 (3.4-12.8)** |
| UCM+SP (N=71) | 0.2 (0-1.3) | 1.3 (0,7-1.5) | 2.4 (1.9-6.5) | 8.2 (4.5-12.8) |
| L2C (N=70) | 0.3 (0.2-0.6) | 0.6 (0.6-4.2) | 3.5 (1.1-9.3) | 7.5 (2.0-12.3) |
| Note. Pre-COVID was defined as participants who completed the study before March 16, 2020 (participants 2001-2175). Post-COVID was defined as participants who completed the study before August 31st (participants 2001-2225). | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Table 10B**: Number of study visits completed between visits 3 and 5. | | | | |
|  | Visits completed between V3 & V5, n(%) | | | |
| 0 Visits | 1 Visit | 2 Visits | 3 Visits |
| ***Pre-COVID-19 protocol (through March 2020, n=166)*** | | | | |
| **Overall** | **28 (16.9)** | **30 (18.1)** | **40 (24.1)** | **68 (41.0)** |
| UCM (N=55) | 12 (21.8) | 13 (23.6) | 12 (21.8) | 18 (32.7) |
| UCM+SP (N=56) | 8 (14.3) | 8 (14.3) | 16 (28.6) | 24 (42.9) |
| L2C (N=55) | 8 (14.6) | 9 (16.4) | 12 (21.8) | 26 (47.3) |
| ***Post-COVID-19 protocol (Through August 2020, n=210)*** | | | | |
| **Overall** | **34 (21.8)** | **34 (15.1)** | **55 (24.4)** | **87 (38.7)** |
| UCM (N=70) | 14 (20.0) | 17 (24.3) | 16 (22.9) | 23 (32.9) |
| UCM+SP (N=71) | 10 (14.1) | 9 (12.7) | 21 (29.6) | 31 (43.7) |
| L2C (N=69) | 10 (14.5) | 8 (11.6) | 18 (26.1) | 33 (47.8) |
| Note. Pre-COVID was defined as participants who completed the study before March 16, 2020 (participants 2001-2175). Post-COVID was defined as participants who completed one or more study visits after March 16, 2020 (participants 2176-2225). | | | | |

# Arrests

|  |  |
| --- | --- |
| **Table 11.** Association between treatment arm and arrest status 12 months after enrollment (n=167). | |
| **Treatment Condition** | **Arrested**  n (row percent) |
| *Overall* | 88 (48.6) |
| UCM (n=57) | 29 (50.9) |
| UCM+SP (n=58) | 28 (48.3) |
| L2C (n=56) | 26 (46.4) |
| Note: Only includes individuals who completed V2 randomization. | |

# Bridge Case Session Minutes

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Table 12A.** Number of Participants Who Used Case Management (Participants 2001 to 2225)1 | | | | |
|  | **Number of Participants (%)** | | | |
| **Total**  **(N=225)** | **UCM**  **(N=70)** | **UCM+SP (N=71)** | **L2C**  **(N=69)** |
| Used at least one session of regular case management | 143 (63.6) | 46 (65.7) | 44 (62.0) | 47 (68.1) |
| Used at least one session of crisis case management | 22 (9.8) | 9 (12.8) | 7 (9.9) | 6 (8.7) |
| Used at least one session of other case management | 90 (40.0) | 29 (41.4) | 27 (38.0) | 31 (44.9) |
| Used **no** forms of Bridge case management | 67 (29.8) | 19 (27.1) | 23 (33.0) | 17 (24.6) |
| Note: Categories of case management are not mutually exclusive, so percentages may exceed 100.  1Excludes participants who missed randomization (V2) date (n=16) | | | | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Table 12B**. Description of Case Management Sessions and Duration (Participants 2001 to 2225) use1 | | | | | |
|  | **Total**  **(N=225)** | **UCM**  **(N=70)** | **UCM+SP**  **(N=71)** | **L2C**  **(N=69)** | | |
| Total Case Management |  |  |  |  | | |
| Total Management Sessions, median(IQR) | 2 (0-9) | 2 (0-9) | 1 (0-8) | 3 (1-10) | | |
| Minutes of Total Management, median(IQR) | 45 (0-240) | 50 (0-245) | 45 (0-215) | 60 (5-305) | | |
| Regular Case Management |  |  |  |  | | |
| Case Management Sessions, median(IQR) | 1 (0-7) | 2 (0-7) | 1 (0-6) | 2 (0-8) | | |
| Minutes of Case Management, median(IQR) | 45 (0-220) | 47.5 (0-245) | 40 (0-195) | 60 (0-265) | | |
| Crisis Case Management |  |  |  |  | | |
| Crisis Management Sessions, median(IQR) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | | |
| Minutes of Crisis Management, median(IQR) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | | |
| Other Case Management |  |  |  |  | | |
| Other Management Sessions, median(IQR) | 0 (0-1) | 0 (0-1) | 0 (0-1) | 0 (0-2) | | |
| Minutes of Other Management, median(IQR) | 0 (0-10) | 0 (0-10) | 0 (0-5) | 0 (0-10) | | |
| 1Excludes participants who missed randomization (V2) date (n=15) | | | | |  |

# Recruitment

**Figure 1A: Recruitment by Month.**



1. Recruitment began on April 17, 2018 and ended temporarily on March 17, 2020 due to COVID-19 and began again on July 6, 2020

2. Graph does not include participants that screened out during baseline assessment

**Average Recruitment:**

*Overall:* **8.4** participants per month

*Pre-COVID-192*: **9.8** participants per month

*Post-COVID-193*: **4.5** participants per month

First

Overall is defined as recruitment averages from 4/17/18-8/31/20

2Pre-COVID-19 if defined as recruitment averaging from 4/17/18-3/16/20

3Post-COVID-19 if defined as recruitment averaging from 3/17/20-8/31/20

**Figure 1B: Monthly recruitment trends stratified by year.**