Summary

We consider an mHealth intervention in which there are momentary treatments intended to affect a proximal response. These effects could be immediate or delayed. They also might change according to or be moderated by the individual’s characteristics and context.

Under certain conditions, immediate and delayed effects can be estimated with existing software. This approach can also assess moderation by a few select variables, without having to correctly model the entire response process.

Data

$t$: treatment occasion, $t \in \{1, \ldots, m\}$

$X_t$: individual and contextual characteristics just before $t$

$A_t$: binary treatment at $t$

$Y_{t+1}$: continuous response following $t$ and before $t+1$

$H_t$: history through $t$: $(X_t, Y_{t-1}, A_{t-1})$

Data treatment effects

$Y_{t+1}(d_t)$ response, had the treatments $d_t$ been provided

$S_0(A_{t-1})$: vector of candidate moderators from $H_{t-1}$ had $A_{t-1}$ been provided

The immediate effect of $A_t = 1$ versus $A_t = 0$ on $Y_{t+1}$ is

$$E[Y_{t+1} | A_t = 1, H_t] - E[Y_{t+1} | A_t = 0, H_t] = S_0(A_{t-1}) \cdot \beta_0$$

This is averaged over any variables in $H_t$ not represented in $S_0$.

The delayed effect of $A_t = 1$ versus $A_t = 0$ on $Y_{t+2}$ is similarly defined:

$$E[Y_{t+2} | A_t = 1, H_t] - E[Y_{t+2} | A_t = 0, H_t] = S_0(A_{t-1}) \cdot \beta_1$$

This is averaged over any variables in $H_t$ not in $S_0$ and future treatment $A_{t+1}$.

If treatments are sequentially randomized

The immediate and delayed treatment effects in terms of the observed data and assume (for parsimony) a linear model:

$$E[Y_{t+1} | A_t = 1, H_t] - E[Y_{t+1} | A_t = 0, H_t] = S_0(A_{t-1}) \cdot \beta_0$$

The probability of receiving a mindfulness-based EMI

$I_t$: indicator that the student completed the preceding EMA

$S_{EMI}$ indicator of increased self-regulation from $t-1$ to $t$

$S_{EMI}$ equal to $1$

The probability of receiving a mindfulness EMI was unknown and modelled with

$$Pr(H_t = \text{EMI}) = \expit(0.69 + 0.02I_t + 0.17urge - 0.28(I_t < 4) + 0.70urge(I_t < 4))$$

Extension and implementation

1. Suppose that the $Pr(H_t = \text{EMI})$ are unknown, but can be modelled by $Pr(H_t = \eta)$. Then use $Pr(H_t = \eta)$ in $w_t(A_t, H_t)$ and correct SEs for sampling error in $\eta$.

2. Suppose at $t$ we also observe $I_t = 1$ when the individual is available to engage with the intervention and $I_t = 0$ otherwise. Then we define effects conditional on ($I_t = 1$) and multiply weight the $w(A_t, H_t)$ by $I_t$.

3. Use standard GEE software only with the independence working correlation structure. Alternative structures, such as AR(1), induce bias.

Simulation

The proximal response was generated from the underlying process:

$$y_{t+1} = \theta(1 + 0.01I_t) + \alpha y_{t+1} + \sum_{k=1}^{12} \beta_k(A_k - \rho_k(H_k)) + \epsilon_{t+1},$$

where $Z$ is drawn from the empirical distribution of the BASICS-Mobile mean-centered baseline smoking rate, $\rho_k(H_k) = 1/3, k = 0, 1$, with correlation $0.5(0.1)^{k-1}$, $\theta = 0.6$ and $\beta_2 = -0.4$. In a weighted regression analysis for the delayed treatment effect, we fit

$$E[Y_{t+2} | A_t, H_t] = \sigma_0 + \alpha y_{t+1} + \sum_{k=1}^{12} \beta_k(A_k - \rho_k(H_k)),$$

with weights given by $\rho = 1/2$ and $\rho_1(H_1) = 1/3$. Scenarios arise from two factors:

1. Working model correct ($\theta = 0$ and $\alpha y_{t+1}$ omitted) or incorrect ($\theta = 0.6$).

2. Presence ($\beta_2 < -0.8$) or absence ($\beta_2 = 0$) of an immediate treatment effect.

AR(1) is the correct correlation structure, but only in the absence of an immediate effect can we estimate $\beta_2 = -0.4$ without bias:

<table>
<thead>
<tr>
<th>Working model</th>
<th>Present</th>
<th>Absent</th>
<th>Present</th>
<th>Absent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immediate effect</td>
<td>0.095</td>
<td>0.150</td>
<td>0.095</td>
<td>0.150</td>
</tr>
<tr>
<td>Correct</td>
<td>0.095</td>
<td>0.150</td>
<td>0.095</td>
<td>0.150</td>
</tr>
<tr>
<td>Incorrect</td>
<td>0.095</td>
<td>0.150</td>
<td>0.095</td>
<td>0.150</td>
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</tbody>
</table>

BASICS-Mobile

Witkiewitz et al. (2014) modified the Brief Alcohol Screening and Intervention of College Students (BASICS; Dimeff 1999) to also target smoking and administer by smartphone. This modality enabled ecological momentary assessment and intervention (EMA and EMI). 30 students used BASICS-Mobile for up to 2 weeks, with 3 EMAs prompts per day. EMAs, following the last two EMAs, contained either general information or mindfulness training. We considered:

- $A_t$: indicator that the student received a mindfulness-based EMI
- $I_t$: indicator that the student completed the preceding EMA
- $Y_{t+1}$: daily smoking rate reported at the EMA following $A_t$
- $S_{EMI}$ indicator of increased self-regulation from $t-1$ to $t$
- $S_{EMI}$ equal to $1$

The probability of receiving a mindfulness EMI was unknown and modelled with

$$Pr(H_t = \text{EMI}) = \expit(0.69 + 0.02I_t + 0.17urge - 0.28(I_t < 4) + 0.70urge(I_t < 4)),$$

where urge indicates an urge to smoke was reported at the EMA preceding $t$.

Effect | Estimate | SE | 95% CI | p-value | Estimate | SE | 95% CI | p-value |
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<thead>
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</thead>
<tbody>
<tr>
<td>Immediate, $t$ self-regulation</td>
<td>$-0.5$</td>
<td>0.76</td>
<td>($-2.0$, $1.1$)</td>
<td>0.553</td>
<td>-2.5</td>
<td>1.21</td>
<td>($-5.0$, $-0.1$)</td>
<td>0.045</td>
</tr>
<tr>
<td>Delayed</td>
<td>$-1.0$</td>
<td>0.59</td>
<td>($-2.4$, $0.2$)</td>
<td>0.100</td>
<td>-2.5</td>
<td>1.21</td>
<td>($-5.0$, $-0.1$)</td>
<td>0.045</td>
</tr>
</tbody>
</table>

The data suggest that the mindfulness-based EMI achieved a reduction in the average next-reported smoking rate, but only when the student was experiencing either a stable or decreased need to self-regulate.

Further work: Time-to-event response

Time-to-event models are typically based on the event counting process. Let $N_t(\omega)$ count the number cigarettes smoked after the $t$th treatment occasion and up to time $u > t$. We can carry out regression analysis of $N_t(\omega)$ via

$$\int_{t-u}^{t} S_A(v)S_\beta(v)dv,$$

which can be fit to the data using local least squares (Aalen 1989). Here $S_A(u) = \int_{t-u}^{t} S_A(v)dv$ represents the cumulative effect of $A_t = 1$ versus $A_t = 0$ on the risk of smoking over $(t, u)$, moderated by $S_t$. We need not specify how the coefficient $\beta_t$ varies with time; its true form may be uncovered by the estimate for $B_t$. 

Advancing biomedical discovery and improving health through mobile sensor big data

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