Novel digital technology supporting sun protection and vitamin D synthesis by using satellite-based monitoring of spectral solar radiation

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Conflicts of interest

• Antony R Young received a consultancy fee paid by siHealth and BASF, including his travel to Brazil and accommodation costs.
• Sergio Schalka, the Clinical Director of Medcin, received a consultancy fee paid by siHealth and BASF for logistics organisation and clinical supervision
• Emilio Simeone, Marco Morelli and Rowan Temple are respectively the CEO, the CTO and the Head of Technology Innovation of siHealth
• Myriam Sohn and Christina Kohlmann are employees of BASF, that provided the study sunscreens
Background

• Solar UVR exposure has risks and benefits
• Hard for individuals to determine optimal solar exposure times because of multiple factors such as:
  • Ultraviolet index (UVI)
  • Skin type
  • Sunscreen use
  • Body surface area exposed
• Apps may be an important health tool but not typically based on real-time UVR data
Study aim

• Evaluate a new app [Sun4Health® by siHealth Ltd (Oxfordshire, UK)]
  • Real-time satellite-based spectral UVR data
  • Based on a siHealth’s patented technology (Patent no. WO 2017/153832)
  • Personalised data input (e.g., personal MED calculated from user profile)
  • Incorporates spectral properties of any sunscreen
  • Personalised advice to balance the benefits and risks of solar exposure
  • Personalised recommendations on sunscreen quantity and on its re-application
  • Creates personalised 3D avatar that provides body-site specific recommendations to avoid sunburn (Sun4Health®-3D version, connected to a wearable device)

• Short break high UVI beach holiday
Study design

• Period
  • 6-8th and 13-15th December 2019 (long weekends)

• Location
  • Santos, Brazil (23.97°S, 46.33°W)

• Volunteers
  • N=59, 18-50 years, Fitzpatrick skin types (FST) I-III

• 3 app option groups (control, Sun4Health®, Sun4Health®-3D)

• Sunscreens provided by BASF

• Erythema and vitamin D status monitored every day
Santos, Brazil
Ground-based solar UVR measurement

- Hotel roof with no shadow
- SUV-E UVR radiometer calibrated for erythemally effective irradiance
- Sampling every second and data archived as mean values per minute and transmitted to a cloud via a dedicated datalogger
- Data used to assess the validity of the satellite based UVR monitored by the Sun4Health® app
Mean daily UVI and ambient SED
Sun4Health® app’s functionalities

- Questionnaire to estimate user’s minimal erythema dose (MED)
- Real-time satellite-based monitoring of erythemal and vitamin D-effective irradiances (CIE action spectra)
- Input data
  - Sunscreen
  - Clothing
  - Environment
- Remaining “safe” exposure times based on 0.7 MED as “100% erythema risk”
- Real time dosimetry of accumulated daily effective vitamin D dose and remaining time to reach “100% vitamin D daily target” (assuming equivalent of 400 IU or 10 µg/day as daily target)
App options (randomly assigned)

- **Group 1**: Control app
  - UVI only (commonly available weather information), with no specific personalised recommendations

- **Group 2**: Sun4Health® app
  - All functionalities of Sun4Health® (without 3D wearable device)

- **Group 3**: Sun4Health®-3D app
  - All functionalities of Sun4Health® plus wearable device for 3D dosimetry
Sun4Health® app’s versions

Sun4Health® (Group 2)

- Sunburn safety time remaining
- Photoageing: Actual daily photoaging accumulated
- Vitamin D: Actual daily vitamin D accumulated

Sun4Health®-3D with wearable device (Group 3)

- Real Time Exposure
- 71% of year’s daily limit

Bluetooth®
Sunscreens

• Provided by BASF
• Range of cosmetic formulations
  SPF = 30, UVA-PF = 12.4
  SPF = 50, UVA-PF = 19.4
• Volunteers had free choice
• Used freely by all the groups (groups 1, 2 and 3)
• Instructions given on optimal use only via the Sun4Health® app (i.e., to groups 2 and 3)
• Sunscreen use weighed
Erythema assessments

- Reflectance spectroscopy (Mexameter® MX MX18WL by Courage + Khazaka Electronic GmbH, Germany)
- Six body sites
  - Right underarm (control)
  - Right and left shoulders
  - Back
  - Right and left abdomen
- Every morning and every afternoon
- Change over whole study period used for data analyses
Vitamin D status

- Blood samples taken 1 day before study and 3 days after (managed by Instituto de Análises Clínicas de Santos, Brazil)
- HPLC tandem mass spectrometry for 25(OH)D$_2$ and 25(OH)D$_3$
Time outdoors, sunscreen use and UVR exposure

<table>
<thead>
<tr>
<th>App group</th>
<th>Time outdoors (h)</th>
<th>Total SS use (g)</th>
<th>Average SPF</th>
<th>Total SED</th>
<th>Est. total SED through SS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean ± SD</td>
<td>Mean ± SD</td>
<td>Mean ± SD</td>
<td>Mean ± SD</td>
<td>Mean ± SD</td>
</tr>
<tr>
<td>1</td>
<td>13.03 ± 3.1</td>
<td>73.77 ± 40.7</td>
<td>43.7 ± 19.1</td>
<td>67.56 ± 8.02</td>
<td>1.63 ± 0.6</td>
</tr>
<tr>
<td>2</td>
<td>12.73 ± 3.3</td>
<td>49.23 ± 33.6</td>
<td>41.6 ± 9.6</td>
<td>66.47 ± 13.01</td>
<td>1.68 ± 0.8</td>
</tr>
<tr>
<td>3</td>
<td>12.72 ± 2.3</td>
<td>60.12 ± 41.0</td>
<td>42.3 ± 9.0</td>
<td>67.52 ± 8.43</td>
<td>1.70 ± 0.7</td>
</tr>
<tr>
<td>All groups</td>
<td>12.82 ± 2.9</td>
<td>60.82 ± 39.2</td>
<td>42.5 ± 9.3</td>
<td>67.18 ± 9.94</td>
<td>1.67 ± 0.7</td>
</tr>
</tbody>
</table>
Δ erythema over 3 days for each body site
Δ erythema over 3 days for all body sites combined

• ANOVA P < 0.05

• Post hoc comparisons
  • Group 1>2 (P = 0.01 or 0.03 after Bonferroni correction)
  • Group 1>3 (P= 0.001 or 0.003 after Bonferroni correction)
  • Group 2=3 (P >0.5)

• Sun4Health® app reduced total body cumulative erythema
Mean difference in vitamin D status

- Serum 25(OH)D$_2$ was below the limit of detection (12 nmol/L) in all cases
- Change in serum 25(OH)D$_3$
  - ANOVA $P > 0.05$
  - Group 3 > 2 > 1
- The use of the Sun4Health® app increased serum 25(OH)D$_3$, but with high interpersonal variation
Study strengths and weaknesses

**Strengths**
- Clinical field study
- High UVI
- Direct monitoring of participants

**Weaknesses**
- Limited sample size
- Short duration
- Participants in close contact and may have influenced each other
- Weather cloudier than expected for season
Conclusions

• The Sun4Health® app (groups 2 and 3) significantly reduced skin erythema (sunburn risk) compared to control group 1.

• The recommendations provided by the Sun4Health® app (groups 2 and 3) have resulted in an increase of the mean serum 25(OH)D₃ level compared to control group 1, but the high interpersonal variation implies that further studies are needed.

• Overall, the results show that the digital Sun4Health® app providing real-time advice is safe to use and can modify behaviour to reduce skin erythema (sunburn) under very high UVI (e.g., from beach activities), yet increasing the level of vitamin D synthesis.
Research team and volunteers
Acknowledgements

• The clinical field study (No. RBR-2MF6QG) was registered on 20th May 2020 with Registro Brasileiro de Ensaios Clínicos (ReBEC), with ethical approval EN19-0771-01 received by the Brazilian Ministry of Health (CONEP)
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• The authors ARY, SS, MM and ES have been the co-Investigators of the study
• The authors are grateful to the volunteers, to the siHealth team that developed the apps, to Markus Schwind and Anja Suckert from BASF for their support
• The siHealth’s Sun4Health® app is distributed as “Sun3P” (“Sun3P-3D” in its 3D version) and commercialised by BASF in the personal care market for providing personalised products